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DEPARTMENT OF CLINICAL INVESTIGATION

ANNUAL RESEARCH PROGRESS REPORT

FISCAL YEAR 1989
VOLUME 2

BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON, TEXAS 78234

SECURITY CLASSIFICATION OF THIS PAGE *(When Data Entered)*

REPORT DOCUMENTATION PAGE

READ INSTRUCTIONS BEFORE COMPLETING FORM

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17. DISTRIBUTION STATEMENT *(of the abstract entered in Block 20, if different from Report)*
n/a

18. SUPPLEMENTARY NOTES
The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.

19. KEY WORDS *(Continue on reverse side if necessary and identify by block number)*
Clinical Investigations; all medical specialties
Publications, presentations;
Detail Summary Sheets (Study Objective; Technical Approach; Progress; Status)

20. ABSTRACT *(Continue on reverse side if necessary and identify by block number)*
Subject report identifies the research activities conducted by Brooke Army Medical Center investigators through protocols approved by the Clinical Investigation Committee, the Institutional Review Board, and the Animal Care Committee and registered with the Department of Clinical Investigation during FY 1988. Report also includes known presentations and publications by the Brooke Army Medical Center staff. The research protocols described were

(continued on reverse side)

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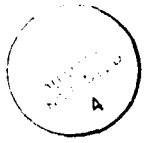
SECURITY CLASSIFICATION OF THIS PAGE *(When Data Entered)*

Block 20. Abstract

conducted under the provisions of AR 40-38, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; USAMRDC 70-25, Use of Volunteers as Subjects of Research; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports; and BAMC Memo 40-98, Department of Clinical Investigation, to insure the medical well-being, preservation of rights and dignity of human subjects who participated in these investigational studies. Research studies involving the use of laboratory animals were conducted under the provisions of AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs.



Detail Summary Sheet

Date: 29 Sep 89 Proj No: A-1-86 Status: Ongoing

Title: Gravitational Effects on Hemodynamics in the Normotensive Primate and Effects of Pressure Suit Inflation

Start Date 26 Mar 86	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Bernard J. Rubal, Ph.D. Robert Schwartz, MAJ, USAF MC Paul Celio, MAJ, USAF MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 12,425.00

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): 1) To describe the effects of the upright posture on waveform contour, regional PWV, Z_{in} and reflection along the aorta.

2) To determine the effect of pressure suit inflation in the upright posture on central systemic pressure, aortic and ventricular dimensions, and cardiac function.

Technical Approach: We evaluated the hemodynamic response to passive upright 70° tilt in 6 baboons to assess the effects of gravity on systemic compliance (C), characteristic aortic input impedance (Zc) and peripheral resistance (R). High-fidelity catheters were used to record aortic root pressure and flow velocity which were digitized at 200 Hz. Thermodilution cardiac outputs were obtained. Data were fitted to a computer model (CM) of a 3-element Windkessel to determine Zc, C, R. There were compared to conventional calculations (CC) of SVR, Fourier analysis for Zc, and time constant of pressure decay for C.

Progress: The data show that the CM fit of pressure and flow to determine Zc, C, and R produces similar results to independent calculations of these parameters. Finally, gravitational stress to passive upright tilt has its most prominent effect on C and little effect on Zc and R.

Detail Summary Sheet

Date: 26 Sep 89 Proj No: A-3-87 Status: Ongoing

Title: Treatment of Chlorine Gas Inhalation Injury with Nebulized Sodium Bicarbonate Using a Sheep Model

Start Date 6 Jan 87	Est Comp Date:
Principal Investigator(vice Singletary) Carey Chisholm, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Alan Morgan, CPT, MC
Key Words: Chlorine gas inhalation	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 4005.92

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To determine the effect of treatment of chlorine gas inhalation injury with nebulized 5% sodium bicarbonate solution, using a sheep model.

Technical Approach: In Phase I, degree of injury induced by chlorine gas will be determined by exposing 10 subjects to chlorine gas, 500 ppm, for various periods of time. Subjects will be anesthetized, intubated and exposed to chlorine gas by insufflation technique as described under Phase II, with arterial blood gas determinations every 30 minutes following exposure for 2 hours. Following chlorine exposure, subjects will e observed for 24 hours, then sacrificed and necropsy performed.

In Phase II, subjects will be divided into 3 groups of eight sheep each. Group A will be exposed to chlorine gas, 500 ppm, for a period of time as determined in Phase I, followed by nebulized normal saline for 5 min. Group B will be exposed to chlorine gas, 500 ppm, for the same period as for Group A, followed b7 5% sodium bicarbonate solution for 5 minutes. Group C will not be exposed to chlorine gas, but will be given nebulized 5% sodium bicarbonate solution for 5 minutes. Groups A and B will begin treatment 30 minutes post chlorine exposure.

Progress: This study remains open for completion of manuscript which is being prepared.

Detail Summary Sheet

Date: 12 Sep 89 Proj No: A-5-87 Status: Terminated

Title: The Effect of Dietary Fiber on the Incidence of Adenocarcinoma Following Ureterosigmoidostomy in Rats

Start Date 2 Apr 87	Est Comp Date:
Principal Investigator William H. Boykin, Jr., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Ian M. Thompson, MAJ, MC Gene B. Hubbard, D.V.M. Marlene Gaines, SGT
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1,781.00

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 4 Oct 89 Results Terminate

Objective(s): To determine if alteration in dietary fiber content decreases the incidence of adenocarcinoma following ureterosigmoidostomy in an animal model.

Technical Approach: One hundred twenty male Sprague-Dawley rats will be obtained, housed and fed standard lab chow and tap water ad lib. On the night before the surgical procedure, all animals will be kept NPO. All animals will undergo ureterosigmoidostomy and then randomized into two treatment arms: one group will be recovered/fed lab chow with a higher fiber content, and the other will receive a diet high in protein and carbohydrates but with minimal fiber. The remainder of the study will be conducted as outlined in the study protocol.

Progress: Study terminated due to lack of progress.

Detail Summary Sheet

Date: 12 Oct 89	Proj No: A-7-87	Status: Terminated

Title: Urodynamic Profile of Three Types of Urinary Reservoirs

Start Date 28 May 87	Est Comp Date:
Principal Investigator William H. Boykin, Jr., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of	Associate Investigators: Ian M. Thompson, MAJ, MC William Ehler, D.V.M.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 4 Oct 89 Results Terminate

Objective(s): 1) To develop an animal model for three basic types of enteral urinary reservoirs.

2) To objectively document with urodynamics the pressure characteristics of the different reservoirs.

Technical Approach: This study will be conducted at the Clinical Investigation Facility, Wilford Hall USAF Medical Center. Fifteen pigs will be randomized into three treatment groups. One group will undergo isoperistaltic/antiperistaltic anastomosis of two segments of ileum, the second group will undergo a similar procedure utilizing large bowel, and the third group will have a reservoir fashioned from a combination of large and small bowel. The technical details will be carried out as outlined in the study protocol.

Progress: Study terminated due to lack of progress.

Detail Summary Sheet

Date: 6 Sep 89 Proj No: A-12-87 Status: Ongoing

Title: Hemodynamic Effects of Anesthetic Induction with Ketamine or Etomidate in Hypovolemic Swine

Start Date 28 Sep 87	Est Comp Date:
Principal Investigator (vice Knight) Charles P. Kingsley, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Kevin Olson, CPT, MC
Key Words: Hypovolemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1166.73

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To determine which anesthetic induction agent provides optimal hemodynamic stability in the presence of acute hypovolemia secondary to hemorrhage.

Technical Approach: The effects of induction doses of etomidate, ketamine, and thiopental were evaluated in acutely traumatized, moderately hypovolemic swine. Twenty-five acutely instrumented swine were mechanically ventilated with 70% nitrous oxide and hemorrhaged to a mean arterial pressure of 40 mmHg. After allowing the animals to stabilize, etomidate 1.2 mg/kg, ketamine 6.0 mg/kg, or thiopental 6.0 mg/kg were administered as a bolus to simulate the induction of anesthesia. Hemodynamic measurements were then made at 1, 5, 15, and 30 minutes after drug injection.

Progress: Data analysis and retrieval system upgraded. Data now being reanalyzed.

Detail Summary Sheet

Date: 6 Sep 89 Proj No: A-13-87 Status: Ongoing

Title: A Comparison of the Effects of Resuscitation from Hemorrhagic Shock with Normal Saline, Hetastarch, Whole Blood, and Hypertonic Saline on Intracranial Pressure, Intracranial Compliance and Cerebral Metabolism

Start Date 28 Sep 87	Est Comp Date:
Principal Investigator Joseph P. Ducey, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery	Associate Investigators: David W. Mozingo, CPT, MC Marlene Gaines, SGT Theopolis Peace, COL, VC
Key Words: Shock, hemorragic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1532.00

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): 1) To establish a pig model of combined hemorrhagic shock and closed head injury, a combination common to both the battlefield and the emergency room.

2) To determine the effect on ICP and cerebral metabolism of using hemodynamic markers (BP, CVP, PAOP) as end points of fluid resuscitation in shock.

3) To compare the effects of fluid resuscitation with different solutions (whole blood, hetastarch, normal saline, and hypertonic saline) on ICP, intracranial compliance and cerebral metabolsim in hemorrhagic shock with epidural mass.

Technical Approach: Following induction of adequate anesthesia, bilateral twist drill holes will be placed in the temporo-parietal regions of the skull. A Fogarty balloon catheter will be placed in the right parietal epidural space and an ICP monitor inserted through the left twis drill hole into the subarachnoid space. Baseline ICP and arterial pressure will be obtained. A pressure-volume curve will be generated utilizing the epidural balloon catheter (EBC). The inflection point (Pi) of this curve will be determined and recorded.

Progress: This study has been placed on hold temporarily. Experiments will resume in the near future.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: A-1-88 Status: Ongoing

Title: The Effect of Lysine on Substance P in Guinea Pigs

Start Date 2 Dec 88	Est Comp Date:
Principal Investigator Eleanor Ayala	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1958.00

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To evaluate the in vivo effect of topical applications of L-lysine on substance P in guinea pigs.

Technical Approach: As outlined in the protocol. Male Hartley guinea pigs have been treated. Three days post treatment, tissue biopsies of inoculated sites and dorsal root ganglia (DRG) have been collected from each animal for immunohistochemical detection of substance P (SP) with a Biotin-strep avidin tagged monoclonal antibody to SP.

The method of Tuchschere and Seybold for the sectioning of tissue on the microtome was used. However, because it is difficult to recover 100% of the sectioned tissue and, because there appeared to be an uneven distribution of neurons in the kidney shaped DRG, an examination of every third tissue section was not an option.

Progress: The collection and processing of skin biopsies and dorsal root ganglia (C1-S1) have been completed. The data are being analyzed. The results may require confirmation of differences with the use of isolated cells.

Detail Summary Sheet

Date: 27 Sep 89 Proj No: A-3-88 Status: Ongoing

Title: Evaluation of Uncemented Canine Hip Prosthesis

Start Date 17 Feb 88	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: William Ehler, D.V.M., Wilford Hall Arnold Penix, MAJ, USAF MC David L. Danley, MAJ, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review _____ Results _____

Objective(s): To develop and refine the techniques of uncemented hip arthroplasty in dogs and evaluate the remodelling of bone around the femoral stem of a titanium prosthesis.

Technical Approach: As outlined in the Company protocol.

Progress: We have had great difficulty in securing 70 kg dogs, but expect to do two more cases in this pilot study.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: A-4-88 Status: Ongoing

Title: A Conscious Baboon (Papio anubis) Model to Study Ventricular Pressure-Volume Relations and Ventricular/Vascular Coupling in Altered Gravitational Environments.

Start Date 14 Apr 88	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: James R. Hickman, COL, USAF MC
Key Words:	Bernard J. Rubal, Ph.D. Paul Celio, M.D. Curtis White
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review Results

Objective(s): 1) Develop a conscious, tethered or lightly sedated, nonhuman primate model conducive to the study of ventricular/vascular hemodynamics using inductance telemetry in flight.

2) Describe ventricular pressure-volume relations and ventricular/vascular coupling supine (zero Gz, Igx) upright (1Gz, zero Gx), 1Gz environments and in microgravity or zero G environments.

2) Assess hemodynamic responses to a high flow, computer-driven pulsatile fluid filled anti-G suit with standard G-gated pulsations vs ECG-gated pulsations.

Technical Approach: Transducers will be applied via thoracotomy. Initial animals will use exteriorized cables. Animals will be trained to accept the tilt table. Pressure flow and crystal cimensions will be collected and converted real time.

Progress: Protocol to keep leads uninfected established. Equipment and four cull animals have been performed. Awaiting arrival of transducers to operaton on the fifth animal and first data animal.

Detail Summary Sheet

Date: 6 Sep 89 Proj No: A-5-88 Status: Ongoing

Title: Use of a Swine Model for Evaluation and Training with the OHMEDA PAC Vaporizer (Draw-over Anesthesia Device)

Start Date 9 May 88	Est Comp Date:
Principal Investigator Charles P. Kingsley, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Kevin Olson, CPT, MC Richard Peterson, CPT, MC Donald Fox, CPT, MC Emil J. Menk, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): 1) To gain experience with the use of this anesthesia delivery system in swine model and acquire physiological data that would be useful in anticipating its performance in human patients.

2) To provide on-going training and familiarization to military anesthesiologists and anesthetists with anesthesia equipment designed for the field environment.

Technical Approach: Swine are randomized to receive halothane, isoflurane, or ethrane using a PAC vaporizer. Anesthetic is provided in increasing concentration with end tidal oxygen, carbon dioxide, and agent concentration recorded at each level. Pulse oximetry and respiratory volumes are monitored, and arterial blood samples are analyzed.

Progress: Study initially completed. Upon evaluation of data, it was determined that the devices need to be recalibrated. The study will resume when this has been done.

Detail Summary Sheet

Date: 6 Sep 89 Proj No: A-6-88 Status: Ongoing

Title: Use of a Swine Model for Evaluation and Training with the PENLON Vaporizer (Draw-over Anesthesia Device)

Start Date 9 May 88	Est Comp Date:
Principal Investigator Charles P. Kingsley, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Kevin Olson, CPT, MC Richard Peterson, CPT, MC Donald Fox, CPT, MC Emil J. Menk, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): 1) To gain experience with the use of this anesthesia delivery system in swine model and acquire physiological data that would be useful in anticipating its performance in human patients.

2) To provide on-going training and familiarization to military anesthesiologists and anesthetists with anesthesia equipment designed for the field environment.

Technical Approach: We will utilize the same approach as outlined in A-5-88.

Progress: Two animals have been evaluated. It is too early to report any meaningful results.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: A-7-88 Status: Completed

Title: Evaluation of Chemexfoliation on Surgical Skin Flaps

Start Date 9 May 88	Est Comp Date:
Principal Investigator David D. Hayes, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Kweon I. Stambaugh, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To evaluate the effect of simultaneous chemexfoliation on the viability of a broad-based skin flap.

Technical Approach: Each of the guinea pigs has had a broad-based random skin flap created. Half had only the flap and half had both the flap as well as chemexfoliation. The animals were anesthetized and punch biopsies taken at regular intervals.

Progress: Addition of chemical peel to acutely raised skin flap caused an overall greater skin flap loss.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: A-8-88 Status: Terminated

Title: Magnesium and Calcium Interaction in the Rat Cardiovascular System

Start Date 1 Sep 88	Est Comp Date:
Principal Investigator John A. Ward, Ph.D.	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Linda Koehler, MA, MT Gene V. Hubbard, D.V.M.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To determine the effect of the Ca/Mg ratio in magnesium deficiency on the function of vascular smooth muscle, contraction will be studied by measuring tension vs. Ca^{++} curves for the abdominal aorta in five groups of rats: 1) magnesium sufficient, 2) magnesium deficient, 3) magnesium deficient, calcium excess, 4) magnesium deficient, calcium deficient, and 5) lab chow.

To determine the effect of Ca/Mg ratio in magnesium deficiency on the hemodynamics of an isolated vascular bed. Hemodynamic alterations will be studied by measuring pressure-flow vs. Ca^{++} curves in five groups of rats as above.

Technical Approach: All animal studies will be conducted at Incarnate Word College Division of Nursing and the Sciences. All procedures will be done as outlined in the study protocol.

Progress: This study was terminated due to inability to obtain the needed funding.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: A-1-89 Status: Terminated

Title: Peirpheral Resistance and Aortic Compliance in Magnesium Deficient Rats

Start Date 6 Dec 88	Est Comp Date:
Principal Investigator John A. Ward, Ph.D.	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Gene V. Hubbard, D.V.M. Linda Koehler, MA
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): 1) To develop interactive software for fitting aortic pressure and flow measurements to a 3 element Windkessel model of the systemic arterial tree, nonsteady-state data obtained from an electrical analog will be obtained and analyzed.

2) To determine the effect of magnesium deficiency on peripheral resistance and arterial compliance, hemodynamic transients in pressure and flow will be obtained by acutely changing heart rate in control and magnesium deficient rats.

Technical Approach: The application model during pressure transients will be tested in an electrical analog of the heart and the 3 element Windkessel. "Left ventricular pressure" will be generated by a waveform generator, a source impedance and a diode as the "aotic valve". Four cycles will be selected from the measured sequence. Analysis will be performed on an IBM-AT microcomputer.

Male Sprague-Dawley rats will be divided into three groups. One group will be placed on a lab chow diet, one on an MgS diet and one on an MgD diet. The remained of the study will be conducted as outlined in the study protocol.

Progress: Software was developed for fitting a three-element Windkessel model to aortic pressure and flow recordings. However, the study was terminated due to inability to obtain funding to conduct the necessary animal studies. The software will be used to support other protocols.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: A-2-89 Status: Ongoing

Title: Comparison of Intravenous Antivenin vs Joint Irrigation in Treating Intra-articular Crotalus Atrox Venom Poisoning in a Rabbit Model

Start Date 6 Dec 88	Est Comp Date:
Principal Investigator Robert L. Norris, Jr., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: William Ehler, D.V.M. Carlin M. Okerberg, MAJ, VC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To compare the degree of protection for articular cartilage and synovial membrane following intraarticular (IA) injection of C. atrox venom in a rabbit model using: (1) intravenously administered antivenin alone; (2) joint irrigation with normal saline alone; (3) intravneous antivenin combined with joint irrigation.

Technical Approach: As outlined in the study protocol.

Progress: None due to inability to go to Wilford Hall to conduct study.

Detail Summary Sheet

Date: 27 Sep 89 Proj No: A-3-89 Status: Ongoing

Title: Evaluation of Bone and Associated Soft Tissue Responses to a Resorbable Polymer Implant in Iatrogenic Proximal Tibial Fractures in Goats: A Pilot Study

Start Date 6 Dec 89	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Stephen J. Peoples, D.V.M. George D. Harrington, MAJ, MC R. Marvin Royster, MAJ, USAF MC John H. Cissik, COL, USAF BSC William Ehler, D.V.M.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To evaluate the fracture healing and general tissues responses to a resorbable polymer intramedullary implant in goats.

Technical Approach: The study will include an experimental group, composed of unilateral iatrogenic proximal tibial fractures with an intramedullary implant of the resorbable polymer, and a control group, composed of the same iatrogenic fracture but without the polymer implant. All fractures, experimental and control, will be stabilized by external casing. The responses of the bone and associated soft tissue and polymer degradation will be evaluated at three postoperative intervals.

Progress: Obtaining protocol approval via USAF has not been achieved.

Detail Summary Sheet

Date: 12 Oct 89	Proj No: A-4-89	Status: Terminated

Title: Capillary Blood Supply to the Fascia and Fat in Pigs

Start Date 6 Dec 89	Est Comp Date:
Principal Investigator Julio E. Ortiz, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Plastic Surgery	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To ascertain the difference in capillary blood supply to fascia and fat in pigs.

Technical Approach: The study has been divided into two parts - Part I to establish the animal burn model and Part II anatomic and histologic analysis of fat and fascial circulation. Yucatan (hairless) pigs weighing approximately 15 kg will be utilized for establishing the burn model. After this has been determined, pigs will be anesthetized and undergo full thickness burns. Eschar will be removed at days 5, 10, 30, 40, 50, and 60 and biopsies of fat and underlying fascia obtained. Histologic analysis of all specimens will be performed and the number of blood vessels noted. At the end of two motnsh animals will be euthanized and complete necropsy performed.

Progress: Study terminated due to PCS of principal investigator.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: A-5-89 Status: Completed

Title: A Comparison of the Electrophysiologic Effects of Small Volume Resuscitation with 7.5% NaCl in 7% Dextran-70 (HSD) with Standard Resuscitation Following Hemorrhage

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator (vice Ducey) James M. Lamiell, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/SICU	Associate Investigators: Glen E. Gueller, SFC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To ascertain the efficacy of small-volume HSD in achieving cerebral resuscitation following severe hemorrhagic shock.

Technical Approach: Nineteen animals are the subject of this study. Each was anesthetized with ketamine, 22 mg/kg IM, and Xylazine, 0.44 mg/kg IM. Solutions of 6T NaCl (HS), 0.9% NaCl (NS), 6% hetastarch (HE), and whole blood (WB) were used to resuscitate swine in hemorrhagic shock(MAP <30 mmHg). The endpoint of resuscitation was normal oxygen delivery (DO_2). Measurements of intracranial pressure (ICP), cerebral perfusion pressure (CPP), and intracranial elastance (ICE) were made in the absence and presence of an epidural mass, created by inflating an epidural balloon.

Progress: HS resuscitation resulted in a lower ICP (5±1 vs. 9±2 (HE), 17±3 (NS), and 10±3 (WB) mmHg; p = .016), and normalization of CPP throughout resuscitation. NS decreased CPP by the end of resuscitation (CPP = 45±4 for NS group, vs. 63±4 (HE), 66±4 (HS), and 6±3 (WB) mmHg; p = .009). ICE fell markedly in the HS group, (a decrease of 12±2 vs. a rise of 5±3 (HE), 2±3 (NS), and 6±3 (WB) mmHg/ml; p = .0005). This improvement was even more dramatic in the presence of an epidural mass (a fall of 21±3 vs. no change (HE, WB) and a rise 4±3 (NS) mmHg/ml; *p = .0005). For hemorrhage accompanied by severe head injury, resuscitation with HS may benefit victims by decreasing ICP and diminishing the effects of intracranial mass.

Detail Summary Sheet

Date: 18 Sep 89 Proj No: A-6-89 Status: Terminated

Title: Adaptation of Ventricular/Vascular Coupling and Arterial Dynamics to Weightlessness in Macaca mulatta

Start Date 10 Feb 89	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Barclay Butler, CPT, MS John A. Ward, Ph.D. Bernard J. Rubal, Ph.D.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): 1) To validate reliability of a combination transducer cuff utilizing a high-fidelity pressure cell and a continuous wave doppler flow probe on the proximal aorta.

2) To evaluate ventricular performance pre-, during and post-flight using direct measurements of stroke volume, peripheral resistance, heart rate, and cardiac output.

Technical Approach: As outlined in the study protocol.

Progress: The study was terminated due to failure to obtain the necessary funding.

Detail Summary Sheet

Date: 18 Sep 89 Proj No: A-7-89 Status: Ongoin

Title: Histopathologic Features of Buried Vaginal Epithelium in the Rabbit

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator Eric J. Zeidman, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): 1) To develop an animal model for buried vaginal epithelium and transcutaneous incorporation of nonabsorbable monofilament suture.

2) To objectively demonstrate the fate of buried vaginal epithelium and incorporated nonabsorbable monofilament suture.

Technical Approach: Nonabsorbable monofilament suture will be placed in a helical fashion through vaginal wall on both sides of the vagina. The ends of the suture will then be passed underneath the vaginal wll and anchored to the ipsilateral abdominal wall under mild tension. One suture will be placed on each side. A vaginal flap will be constructed on one side of the vagina and brought over the top of the helical vaginal suture already created. This buried vaginal epithelium and nonabsorbable monofilament suture knot will serve as the study specimen.

Progress: During the performance of the protocol, it was determine that the flaps created were tearing apart so that no vaginal epithelium was remaining buried as planned. It was additionally discovered that a layer of tissue never before described exists in the submucosa of the urogenital sinus of the rabbit. Because the original question posed in the project remains unaswered, the protocol has been amended. The flap technique used on the first set of rabbits has been modified to ensure that the flap remains intact for the duration of the study.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: A-8-89 Status: Ongoing

Title: The Effect of Low Dose Dopamine on Renal Blood Flow Following Prolonged Renal Ischemia

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator (vice Ducey) James M. Lamiell, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/SICU	Associate Investigators: Glen E. Gueller, SFC Joseph P. Ducey, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To determine the efficacy of low dose dopamine in enhancing renal blood flow (RBF) following unilateral renal artery occlusion in rabbits.

Technical Approach: RBF will be measured bilaterally throughout the study. Renal artery occlusion for 30 minutes will be achieved unilaterally using an hydraulic occluder. Animals will be divided into two groups. In Group A, dopamine will be infused at 2 micrograms/kg/min and RBF measured again, comparing the effect of dopamine on the normal and the post-ischemic kidney. Group B will receive D5W placebo. Cardiac output (CO) will be measured continuously using an aortic root probe so that RBF can be expressed as a percentage of CO as well as an absolute flow rate (ml/min). Hepatic artery flow also will be measured as a separate marker of DAS effect on splanchnic flow. Post-ischemic RBF will be compared between Groups A and B in terms of absolute flow and as a prcent of CO. Left and right renal inulin clearance will be measured at baseline and after renal artery occlusion. Total clearance before and after occlusion will be compared as will relative clearance of the left and right kidneys.

Progress: Two rabbit cadavers were obtained and dissected to achieve expertise in the required dissection. Additionally, three rabbits have been anesthetized and the required procedures performed to standardize the animal model. Data accumulation will start in the near future.

Detail Summary Sheet

Date: 18 Sep 89 Proj No: A-9-89 Status: Ongoing

Title: Cardiac Response to Semistarvation and Refeeding

Start Date 5 May 89	Est Comp Date:
Principal Investigator John A. Ward, Ph.D.	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Invstigation	Associate Investigators: Eleanor A. Young, Ph.D., UTHSC-SA
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): 1) To participate in a comprehensive study of the effect of SS and RF on the gastrointestinal tract and the heart that will include measurement of cardiac Ca, K, P, Zn, Cu and Mg concentrations, histology of cardiac tissue, and detailed analysis of cardiac ultrastructure by electron microscopy.

2) To study semistarvation (SS) and subsequent refeeding (RF) in a systemic, controlled animal model, the rat.

3) To monitor cardiac function serially by screening electrocardiograms for arrhythmias.

Technical Approach:

Progress: Funding has been obtained from the National Institutes of Health. A technician has been trained in the technique for recording electrocardiograms from rats. Data colleciton began on 14 August 1989 in the laboratory of Dr. Eleanor A. Young.

Detail Summary Sheet

Date: 28 Sep 89	Proj No: A-10-89	Status: Ongoing

Title: Flow Cytometric Analysis of Guinea Pig Dorsal Root Ganglion Cells

Start Date 5 May 89	Est Comp Date:
Principal Investigator Eleanor Ayala, MT	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Janice Grassel, MT
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 942.45

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To analyze guinea pig dorsal root ganglia cell populations on the basis of cell size, cytology, and peptide immunoreactivities by flow cytometric technique and to determine the distribution of substance P immunoreactive cells in the doral root ganglia of the guinea pig.

Technical Approach: The study will contain two parts. The first part will consist of experiments to characterize the DRG neuronal cell populations of the normal untreated GP by flow cytometric analysis and establish norms for that technique. The second set of experiments will characterize, by flow cytometric analysis, the DRG neuronal cell populations of the lysine treated GP for comparison with corresponding DRG C1-S1 of the controls. Chracterization of the DRG neuronal cell population at the various segmental levels will include determination of the percent populations of large, intermediate, and small cells and the biochemical contents of the cells.

Progress: Experiments to characterize the DRG cell populations of normal untreated GP have been initiated. DRGs from six GP have been collected, weighed, digested and fixed, or fixed and digested. Total numbers of cells from each of 348 DRGs have been counted manually and on the Coulter ZM. Since the Coulter ZM also gives the cell diameters that data was collected on the ZM channelyzer. Several samples have been run through the flow cytometer. The data is being analyzed before proceeding from the second set of experiments.

Detail Summary Sheet

Date: 18 Sep 89 Proj No: A-11-89 Status: Ongoing

Title: Physiologic, Anesthetic, and Mechanical Effects on Neurogenic Motor Evoked Potentials in a Porcine Model.

Start Date 12 Jun 89	Est Comp Date:
Principal Investigator Luke Short, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Richard E. Peterson, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To determine the effects of individual physiologic factors (hypercarbia, hypocarbia, hypotension, and hypothermia) on the latency and amplitude of Neurogenic MOtor Evoked Potentials (NMEP's).

Technical Approach: Each pig will be anesthetized with IV ketamine. A 30 minute time interval will be allowed for steady state to be achieved. Monitoring will include capnography, pulse oximetry, ECG, rectal temperature, arterial blood gases, and transduced pressures of the femoral artery, pulmonary artery and central venous pressure.

Progress: After four early trials we have had excellent technical results in obtaining response (NMEP). There seems to be little change in NMEP with changes in PCO_2. With severe hypotension 30 MAP there is a slight decrease in amplitude and increase in latency. Hypothermia <32°C causes abrupt and marked changes in amplitude/latency. The next phase will evaluate anesthetic agents and their effect on NMEPs.

Detail Summary Sheet

Date: 18 Sep 89 Proj No: A-12-89 Status: Ongoing

Title: Bronchoalveolar Lavage as a Diagnostic Tool in Bacterial Pneumonia of Young Piglets

Start Date 10 Jul 89	Est Comp Date:
Principal Investigator Stephen Inscore, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: William Ehler, D.V.M.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To determine whether bronchoalveolar lavage (BAL) can reliably and accurately determine the etiology of acute bacterial pneumonia in young piglets when compared to lung biopsy as well as currently accepted modes of diagnosis.

Technical Approach: Twenty young piglets of either sex will be studied - 10 with and 10 without endotracheal intubation prior to BAL. Each animal will be infected blindly with one of two common bacteria causing acute pneumonia in children and serial chest x-rays taken until a pneumonic infiltrate develops. BAL will be performed using standard procedures in the uninfected, normal lung and then in the infected lung. Collected fluid will be processed in a standard manner and analyzed for total cell number, differential, gram stain and quantitative bacterial cultures.

Progress: This is a new study. No reportable data are available at this time

Detail Summary Sheet

Date: 25 Sep 89 Proj No: A-13-89 Status: Ongoing

Title: Effects of Ketamine, Isoflurane, Halothane, and Ethrane on Myocardial Contractility and Function in Hypovolemic Swine

Start Date 10 Jul 89	Est Comp Date:
Principal Investigator Sanford Silverman, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Charles P. Kingsley, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): A comparison of hemodynamic, myocardial and biochemical effects of anesthetic levels of ketamine, halothane, ethrane, and isoflurane in normovolemic and hypovolemic swine.

Technical Approach: Pressure/diameter loops will be constructed from sonomicrometer data and ventricular pressure recordings. Alterations in contractility as evidenced by changes in end-systolic elastance in response to these anesthetic agents will be described. Both normovolemic and hypovolemic animals will be studied. Biochemical markers of circulatory perfusion, serum lactate levels and catecholamine levels will be studied.

Progress: Experimentation has begun. No data are available at this time.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: A-14-89 Status: Ongoing

Title: Study of Feral Domestic Cats (Felis domestica) for Lyme Spirochetes at Fort Sam Houston and Camp Bullis, Texas

Start Date 10 Jul 89	Est Comp Date:
Principal Investigator Zia A. Mehr, MAJ, MS	Facility Brooke Army Medical Center
Dept/Svc Preventive Medicine Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To evaluate the current and potential threat of Lyme disease in relation to feral domestic cats and fleas at FSH and Camp Bullis, TX.

Technical Approach: Blood was drawn and fleas were collected from the stray feral cats which were held for the required three days. Collected specimens were submitted to the Bureau of Laboratories, Texas Department of Health, Austin, TX. Blood specimens were examined for the presence of Borrelia burgdorferi; Rickettsia of Borrelia burgdorferi and Rickettsia typhi.

Progress: To date 18 feral domestic cats were examined. Three cats were found with high titer for Lyme spirochete 1:128; 1:128; and 1:256. From fleas examined none were found to be infective with Borrelia burgdorferi or Rickettsia typhi.

Detail Summary Sheet

Date: 2 Dec 88 Proj No: T-4-82 Status: Terminated

Title: Neonatal Chest Tube Insertion Utilizing Rabbit Model

Start Date 19 May 83	Est Comp Date:
Principal Investigator (vice Parry) Richard T. Takao, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To allow practice in recognition and prompt appropriate response to a neonate with life-threatening pneumothorax.

Technical Approach: Following demonstration of chest tube insertion by the instructor, subsequent practice is carried out by the students. Insertion of appropriate sized chest tubes is carried out after the instructor has discussed methods, sites and complications of chest tube insertion.

A new protocol is being prepared and will be submitted in the near future.

Progress: This study was terminated due to failure to submit a revised protocol.

Detail Summary Sheet

Date: 2 Dec 88 Proj No: T-5-82 Status: Terminated

Title: Kitten Intubation Laboratory

Start Date 23 Jun 82	Est Comp Date:
Principal Investigator (vice Parry) Richard T. Takao, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Howard S. Heiman, MAJ, MC John B. Woodall, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To allow all persons delivering health care to newborn infants to become familiar with intubation techniques.

Technical Approach: Intubation technique is demonstrated and supervised by the instructor as outlined in the training protocol.

This study is being revised and will be submitted in the near future.

Progress: This study was terminated due to failure to submit revised protocol.

Detail Summary Sheet

Date: 2 Oct 89 Proj No: T-2-85 Status: Ongoing

Title: Utilization of Goats for Training Special Forces Aidman

Start Date 1 Feb 85	Est Comp Date:
Principal Investigator (vice Matthews) David L. Rubla, CPT, VC	Facility Special Forces School, Fort Bragg, NC
Dept/Svc Department of	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 31 Jan 89 Results Continue

Objective(s): To conduct training of the special forces aidman in the care of high velocity ballistic wounds.

Technical Approach: Training is conducted as outlined in the study protocol. Approximately 200 animals are used per class with approximately two thousand goats used annually.

Progress: During this period 160 studies were trained.

Detail Summary Sheet

Date: 18 Sep 89	Proj No: T-7-86	Status: Ongoing

Title: Mouse Inoculation Test (MI) - Rabies Diagnosis

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator Daniel Guerrero	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To establish and maintain a standing procedure for the MI test as a means of diagnosis for rabies vitus and as a confirmation of the more rapid fluorescent rabies antibody (FRA) test.

Technical Approach: As outlined in the training protocol.

Progress: Approximately 265 mice were utilized during FY 89 for MIC testing.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: T-3-86 Status: Terminated
Title: Urologic Microsurgery - A Training Protocol

Start Date 6 Feb 86	Est Comp Date:
Principal Investigator (vice Thompson) Eric J. Zeidman, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: John Norbeck, CPT, MC Francisco R. Rodriguez, COL, MC Theopolis Peace, COL, VC Marlene Gaines, SGT
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:
Total Number of Subjects Enrolled to Date:
Date of Periodic Review 4 Oct 89 Results Terminate

Objective(s): To train Urology Residents at BAMC the techniques used in microsurgery.

Technical Approach: In the first phase, the trainee will learn basic suturing techniques using the operating microscope and a cut rubber glove to imitate tissue. The second phase will teach the techniques of microscopic reanastomosis of the vas deferens. The third phase will teach the technique of microvascular anastomosis.

Progress: Study terminated due to failure to conduct training on a regularly scheduled basis.

Detail Summary Sheet

Date: 18 Sep 89 Proj No: T-8-86 Status: Ongoing

Title: Production of Positive and Negative Controls for Rabies FA Test

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator Daniel R. Guerrero	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 31 Jan 89 Results Continue

Objective(s): To provide provie positive and negative control slides for use in the fluorescent rabies antibody (FRA) test and to provide a means of confirming that the procedure of directly tagging rabies virus in a brain impression is specific and the fluorescent intensity is optimized.

Technical Approach: As outlined in the training protocol.

Progress: Approximately 9 mice were utilized during FY 89 for preparing rabies infected and uninfected mouse brain tissue slide impressions.

Detail Summary Sheet

Date: 27 Sep 89	Proj No: T-9-86	Status: Ongoing

Title: Orthopaedic Microsurgery - A Training Protocol

Start Date 29 Apr 86	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 66.30

Number of Subjects Enrolled During Reporting Period: 50

Total Number of Subjects Enrolled to Date: 50

Date of Periodic Review 27 Sep 89 Results Continue

Objective(s): To train Orthopaedic Residents and maintain Orthopaedic Staff expertise at BAMC in the techniques used in microsurgery.

Technical Approach: The protocol is broken up into four phases. In the first phase, the trainee will learn basic suturing techniques using the operating microscope. The second phase will teach the techniques of microvascular anastomoses of arteries and veins, and vein grafts. The third phase will teach the technique of microneurorrphaphy, and the four phase will teach the technique of ree tissue transfer using microvascular anastomoses.

Progress: Improvement in surgical techniques have been realized, and improvement in patient care has been noted. This skill (microsurgery) is a mission-essential skin for orthopaedic surgeons.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: T-10-86 Status: Ongoing

Title: Supervised Basic Abdominal and Vascular Surgical Experience

Start Date 29 Apr 86	Est Comp Date:
Principal Investigator(vice Rosenthal) Michael J. Walters, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/General Surgery	Associate Investigators: Robert Solenberger, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 910.00

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 31 Jan 89 Results Continue

Objective(s): 1) To provide basic proficiency to junior housestaff in the handling of the GI and vascular systems before actually operating on humans.

2) To increase the proficiency of more senior surgeons in the performance of seldom performed procedures, so as not to lose their skills.

3) To learn new techniques and operations on animals before starting to use them on humans.

Technical Approach: Training is conducted as outlined in the protocol.

Progress: Training of 6 residents is conducted bi-monthly.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: T-11-86 Status: Ongoing

Title: Microsurgery Training Protocol for Plastic Surgery Staff, Residents and Rotators.

Start Date 29 Apr 86	Est Comp Date:
Principal Investigator Julio E. Ortiz, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Plastic Surgery	Associate Investigators: Robert N. Young, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 347.00

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To familiarize plastic surgeons of microsurgical procedures with the use and care of microscope and microsurgical instruments, and techniques of microsurgery.

Technical Approach: Training is conducted as outlined in the study protocol.

Progress: Training continues on a regularly scheduled basis.

Detail Summary Sheet

Date: 12 Oct 89 | Proj No: T-12-86 | Status: Terminated

Title: Urology Surgical Training Protocol

Start Date 29 Apr 86	Est Comp Date:
Principal Investigator Francisco R. Rodriguez, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words:	Eric S. Zeidman, MAJ, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1,750.00

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 4 Oct 89 Results Terminate

Objective(s): To improve the technical skills of Urology Service residents in performing procedures essential to the specialty of Urology.

Technical Approach: As outlined in the training protocol.

Progress: Study terminated due to failure to conduct training on a bi-monthly basis.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: T-13-86 Status: Ongoing

Title: Swine Model for Technical Procedure Training of Emergency Medicine Residents

Start Date 29 Apr 86	Est Comp Date:
Principal Investigator Carey D. Chisholm, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 2,450.00

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 31 Jan 89 Results Continue

Objective(s): To develop familiarity and competency in performing life saving technical skills applicable to the Emergency Room environment.

Technical Approach: Training is conducted as outlined in the study protocol.

Progress: Training of residents in frequently used emergency procedures continues on a monthly basis.

Detail Summary Sheet

Date: 27 Sep 89 Proj No: T-14-86 Status: Terminated

Title: Cardiothoracic Surgery Service Porcine Surgery

Start Date 12 Jun 86	Est Comp Date:
Principal Investigator Brent A. Grishkin, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators:
Key Words:	Richard M. Briggs, MAJ, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 420.00

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 31 Jan 89 Results Continue

Objective(s): 1) To provide operative experience for cardiothoracic and rotating general surgery residents in procedures not generally available in clinical settings.

2) To provide practical experience prior to initial human clinical experience.

3) To provide experience for clinical perfusion trainee.

Technical Approach: Training is conducted as outlined in the study protocol.

Progress: This protocol was terminated due to failure to conduct training sessions during FY 89.

Detail Summary Sheet

Date: 15 Sep 89	Proj No: T-1-87	Status: Ongoing

Title: Military Working Dogs utilization in teaching first aid, bandaging, gastric tube passage and subcutaneous injections of medications to kennel masters

Start Date 19 Nov 86	Est Comp Date:
Principal Investigator George E. Moore, CPT, VC	Facility Academu of Health Sciences
Dept/Svc Department of Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 31 Jan 89 Results Continue

Objective(s): To familiarize kennel supervisors on treating medical emergencies on military working dogs in the event a veterinarian and/or animal care specialist is not available.

Technical Approach: Training is conducted as outlined in the training protocol.

Progress: Training was conducted on a regularly scheduled basis of eight dogs per month.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: T-2-87 Status: Ongoing

Title: Anesthesiology for ANC Officers Course (6F-66F)

Start Date 6 Feb 87	Est Comp Date:
Principal Investigator Gary Zarr, LTC, AN	Facility Academy of Health Sciences
Dept/Svc Department of Nursing	Associate Investigators: Jeff Serogrham, LTC, AN
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To augment/enhance the formal platform instruction students receive in their medical pharmacology and physiology courses.

Technical Approach: Training is conducted as outlined in the study protocol.

Progress: 36 students were trained during FY 89.

Detail Summary Sheet

Date: 18 Sep 89 Proj No: T-3-87 Status: Ongoing

Title: Abdominal Surgical Experience - Gynecology Service

Start Date 19 Feb 87	Est Comp Date:
Principal Investigator Clifford Hayslip, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 420.00

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 31 Jan 89 Results Continue

Objective(s): To provide hands-on surgical experience (for obstetrics and gynecology residents) in emergent surgical techniques.

Technical Approach: Training conducted as outlined in the training protocol.

Progress: Training of 2 residents has been conducted on a regularly scheduled basis. AT present, however, due to scheduling changes within the Dept. of Ob-Gyn, we have been unable to utilize the animal lab for the past 6-8 months. We are currently attempting to reschedule our allotted time so that we may again continue the resident training in the animal lab.

Detail Summary Sheet

Date: 15 Sep 89 Proj No: T-4-87 Status: Ongoing

Title: Canine Utilization for Rigid Endoscopic Training

Start Date 2 Mar 87	Est Comp Date:
Principal Investigator (vice Wittich) Jesse Moss, Jr., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): 1) To provide hands-on experience to residents in Otolaryngology and Thoracic Surgery, (and possibly general surgery) in the art of rigid endoscopy.

2) To ultimately increase the quality of care to our endoscopy patients by decreasing their surgical risks through laboratory training.

3) To simulate the scenario of an esophageal or tracheobronchial foreign body, in a live, anesthetized animal, for the purpose of developing endoscopic foreign body removal skills.

Technical Approach: Training conducted as outlined in the protocol.

Progress: There were 62 participants in the course. The course received high marks on the critique sheets, and was truly a successful endeavor. This course is critical to the teaching program and allows us an effective laboratory to teach residents the proper, safe methjod of passing an esophagoscope and bronchoscope and the use of CO_2 laser in the larynx. The course has immeasurable benefits in that proper training in endoscopy surgery prevents the dreaded possible complication of a ruptured esophagus or bronchus and CO_2 laser complication.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: T-5-87 Status: Completed

Title: Utilization of Goats for Training of DOD Medical Department Officers for the Combat Casualty Care Course (C-4).

Start Date 13 May 87	Est Comp Date:
Principal Investigator (vice Pasch) Roy J. Hobbs, CPT, MS	Facility Academy of Health Sciences
Dept/Svc Training Division, C-4 Task Force	Associate Investigators: John Sheffield, John, SSG
Key Words:	Rick Somers, LTC, VC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 31 Jan 89 Results Continue

Objective(s): To provide training in trauma resuscitation.

Technical Approach: Students are trained to do procedures such as cricothyroidotomy, tracheotomy, tube thoracostomy, cardiac repair, aortic cross clamping, venous cutdown, peritoneal lavage, etc. as outlined in the training protocol.

Progress: This study has been replaced by protocol T-1-89.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: T-6-87 Status: Ongoing

Title: Utilization of Goats for the Training of Physicians and Physician Assistants in the Advanced Trauma Life Support Instructor Course and Warrant Officer Candidates in the Military Physician Assistant (PA) Course

Start Date 13 May 87	Est Comp Date:
Principal Investigator (vice Wohler) David A. Roberts, LTC	Facility Academy of Health Sciences
Dept/Svc Medicine and Surgery Division	Associate Investigators: Richard J. Lowney, CW4
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To improve trauma management skills of non emergency personnel.

Technical Approach: Training is conducted as outlined in the protocol.

Progress: During FY 89, 68 PA students and ATLS instructors were trained.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: T-7-87 Status: Ongoing

Title: Utilization of Goats for Training of 91B Medical NCO for the Medical NCO Course

Start Date 13 May 87	Est Comp Date:
Principal Investigator (vice Pixley) Gretchen Mayes, MAJ, AN	Facility Academy of Health Sciences
Dept/Svc Combat Medical Specialist Division	Associate Investigators: Claude Kucinskis, CPT
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 31 Jan 89 Results Continue

Objective(s): To improve trauma management skills of 91B Medical NCO.

Technical Approach: Training conducted as outlined in the protocol.

Progress: During FY 89, 1278 NCOs completed the course.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: T-1-88 Status: Ongoing

Title: Oculoplastic Seminar and Laboratory and Wound Closure

Start Date 7 Mar 88	Est Comp Date:
Principal Investigator Robert A. Mazzoli, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: Calvin E. Mein, LTC, MC Donald A. Hollsten, LTC, MC Arthur T. Glover, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 31 Jan 89 Results Continue

Objective(s): Provide advanced proficiency to members of the Brooke Army Medical Center House Staff in primary repair of oculoplastic wounds, learn new techniques and operations on animals before starting to use them on humans, and apply the principles of oculoplastic closure and management of ocular and oculoplastic *trauma*.

Technical Approach: Procedures performed include various types and depths of skin surface incisions and wounds, with subsequent closure utilizing flaps, grafts, and Z-plasties.

Progress: Training of ophthalmology residents will be conducted on an annual basis.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: T-1-89 Status: Ongoing

Title: Utilization of Goats for Training of DOD Medical Department Officers for the Combat Casualty Care Course (C4B)

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator (vice Hobbs) Samuel M. Steele, CDR, USN, MC	Facility Academy of Health Sciences
Dept/Svc Training Division, JMRTC	Associate Investigators: William J. Foody, COL, USAF, MC Roy J. Hobbs, CPT, USAF
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To provide training for gynecologists and urologists in abdominal surgical procedures.

Technical Approach: This course encompasses a formal 3 day curriculum including the Amercian College of Surgeons' Approved Advanced Trauma Life Support course as well as war surgery specific lectures and abdominal surgical procedures. Surgical procedures performed during this training course will not include wound debridement as the goats will not be rounded.

Progress: 2993 students were trained during FY 89 (2111 - C4 and 382 - C4b).

Detail Summary Sheet

Date: 29 Sep 89 Proj No: T-2-89 Status: Ongoing

Title: Utilization of Goats for Training Veterinary Corps Officers, Veterinary Service Warrant Officers and Veterinary Service Enlisted Personnel in the Veterinary Service in the Theater of Operations Course (VESTO) (6G-F2)

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator (vice Bruestle) Robert G. Hicks, LTC, VC	Facility Academy of Health Scineces
Dept/Svc Veterinary Science Division	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To train individuals in proper procurement of animals, humane care of animals for laboratory use, and humane euthanasia with proper disposal of euthanized animals following completion of the training class.

Technical Approach: Classes in the above mentioned objectives will be conducted as outlined in the study protocol.

Progress. 5 veterinary corps officers, 0 veterinary service warrant officers and 14 veterinary service enlisted personnel were trained during FY 89.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: T-3-89 Status: Ongoing

Title: Pediatric Intubation Training Utilizing the Feline Model

Start Date 15 Sep 89	Est Comp Date:
Principal Investigator Stephen C. Inscore, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To teach physicians and other health care professionals the basic knowledge and endotracheal intubation skills required to resuscitate a neonate (newborn) or infant.

Technical Approach: The laboratory exercises will concentrate on developing the health professional's confidence in establishing an airway. Each individual will be required to intubate a cat employing a laryngoscope and endotracheal tube three times for physicians and one time for nurses or other personnel who are not required to intubate on the job. Two groups of students will be arranged: the first group will attend a didactic in-service on proper use of airway adjuvant and airway contro while the second will attend the Cat Intubation Laboratory. At least one instructor will teach the in-service and at least two instructors wil teach the Cat Intubation laboratory. Anesthesia will be maintained throughout the procedure.

Progress: Training will start in late October or early November.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 7804 Status: Ongoing

Title: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin, and Mitomycin-C (FAM) vs Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma.

Start Date FY 78	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Gastric adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): *To determine the efficacy of adjuvant chemotherapy with 5-FU, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TNM stage-groups IB, IC, II and III gastric adenocarcinoma compared to potentially curative surgery alone.*

Technical Approach: Eligible patients must have localized lesions at least extending into the submucous and involving any of the deeper layers with the maximum allowable penetration into but not through the serosa; localized lesions extending through serosa, with or without direct extension to contiguous structures; a lesion diffusely involving the wall of the stomach with or without metastases to immediately adjacent perigastric nodes or a localized lesion of any depth with metastases to perigastric nodes in the immediate vicinity; a localized or diffuse lesion with metastases to perigastric nodes distant from primary.

Therapy will follow the schema outlined in the study protocol.

Progress: 80 patients have been evaluated for toxicity to FAM. One patient had a fatal cardiac toxicity, 3 patients had Grade 3 cardiac toxicities and two patients experienced Grade 4 thrombocytopenia. The miscellaneous toxicities were moderate pulmonary fibrosis and moderate microangiopathic-hemolytic anemia.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 7808 Status: Ongoing

Title: Combined Modality Treatment for Stages III and IV. Hodgkin's Disease MOPP # 6.

Start Date FY 1979	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Hodgkin's Disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 13

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To attempt to increase the complete remission rate induced with MOP-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a PR at the end of 6 cycles of MOP-BAP.

2) To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission durations over a no further treatment group when CR has been induced with 6 cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

Technical Approach: Therapy will follow the schema outlined

Progress: This study is closed to new patient accrual. However, it will remain open for followup purposes.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 7827 Status: Ongoing
Title: Combined Modality Therapy for Breast Carcinoma, Phase III.

Start Date FY 80	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast Carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1
Total Number of Subjects Enrolled to Date: 61
Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1. To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus chemotherapy and oophorectomy.

2. To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, using combination chemotherapy plus tamoxifen versus tamoxifen alone versus combination chemotherapy alone.

3. To compare the disease-free interval and recurrent rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy.

4. To compare the effect of these various adjunctive therapy programs upon the survival patterns of such patients.

5. To correlate the ER status with disease-free interval and survival.

Technical Approach: All patients must have had a radical or modified radical mastectomy with histologically proven breast cancer and with one or more pathologically proven axillary nodes. Primary neoplasm and clinically apparent axillary disease must be completely removed. Pretherapy studies must reveal no evidence of metastatic disease or involvement of the other breast. Therapy will follow the schema outlined in the study protocol.

Progress: The premenopausal trial should reach its necessary accrual by the end of this year. The postmenopausal trial will be closed as soon as the replacement trial has been activated. A publication describing the results of the ER-negative component to the trial will be done in the next year. This study has been closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8094 Status: Completed

Title: Radiotherapy With and Without Chemotherapy for Malignant Mesothelioma Localized to One Hemithorax, Phase III.

Start Date 22 May 81	Est Comp Date:
Principal Investigator: (vice Mills) Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Mesothelioma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 6

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To evaluate, in a randomized prospective manner, the efficacy of Adriamycin in improving the disease-free interval in patients who will receive hemithoracic radiotherapy for Stage I pleural mesothelioma.

2) To further define prospectively the efficacy of radiotherapy to the involved hemithorax in patients with pleural mesothelioma.

Technical Approach: Eligible patients will have histologically confirmed malignant mesothelioma of the pleural cavity. Patients with measurable disease or evaluable disease as well as those in whom all gross disease has been resected will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been two lethal and four life-threatening toxicities of those patients evaluated for radiation therapy toxicities. Six complete and 16 partial responses have been observed from radiation therapy. One patient had life-threatening leukopenia on the Adriamycin arm of the study. At the current rate of accrual and ineligibility.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8216/38 Status: Ongoing

Title: Comparison of BCG Immunotherapy and Adriamycin for Superficial Bladder Cancer, Phase III.

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Bladder	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the effectiveness of intravesical BCG immunotherapy with intravesical adriamycin chemotherapy with respect to disease-free interval and two-year recurrence rate.

2) To compare the toxicity of topical immunotherapy and chemotherapy.

3) To obtain experience regarding disease-free interval and the recurrence rate in patients who develop tumor recurrence and are then crossed over to the alternative treatment arm.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8229 Status: Ongoing

Title: Combined Modality Therapy for Multiple Myeloma, VMCP-VBAP for Remission Induction Therapy: VMCP + Levamisole vs Sequential Half-Body Radiotherapy + Vincristine-Prednisone for Maintenance or Solidation. Evaluation ..... Phase II

Start Date FY 1983	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Myeloma, multiple	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 18

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the effectiveness of two intermittent pulse schedules of the chemotherapy combination of Vincristine, Melphalan, Cyclophosphamide and Prednisone (VMCP) plus Vincristine, BCNU, Adriamycin and Prednisone (VBAP) (alternating versus syncopated) for the induction of remissions in previously untreated patients with multiple myeloma.

2) For patients proven to achieve remission (at least 75% tumor regression after induction), to compare the value of 12 months of chemoimmunotherapy maintenance, VMCP + Levamisole, versus a consolidation program consisting of sequential half-body radiotherapy along with Vincristine and Prednisone followed by unmaintained remission.

3) For patients who only achieve improvement (50%-74% tumor regression) on chemotherapy induction, to determine whether sequential half-body radiotherapy with Vincristine

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8294 Status: Ongoing

Title: Evaluation of Adjuvant Therapy and Biological Parameters in Node Negative Operable Female Breast Cancer.

Start Date FY 1983	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast Node Negative	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 33

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To assess the impact of short-term intensive chemotherapy with CMFP to prevent disease recurrence and prolong survival in N- patients with any size ER- tumor and N- patients with ER+ tumors whose pathological size is greater than or equal to 3 cm.

2) To assess the impact of surgical procedures, ER status, menopausal status and tumor size.

3) To develop guidelines referable to histopathological features of N- tumors which are reproducible and assess their prognostic impact for disease-free survival and survival.

4) To assess the value to CEA in predicting recurrence and survival rates.

5) To assess the natural history of a subgroup with N-, ER+ small tumors.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Status: This study is closed to new patient accrual, open for followup [illegible]

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8300 Status: Ongoing

Title: Treatment of Limited Non-Small Cell Lung Cancer: Radiation vs Radiation plus Chemotherapy (FOMi/CAP), Phase III.

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Non-small cell lung cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 10

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare combination chemotherapy plus radiotherapy to radiotherapy alone for patients with limited, non-small cell lung cancer (NSCLC) in a randomized study with stratification for known important prognostic factors with regard to response rate, response duration and survival duration.

2) To determine the toxicity of radiotherapy plus FOMi/CAP relative to radiotherapy alone for patients with limited NSCLC.

3) To evaluate the responsiveness of small tumor burdens to FOMi/CAP (i.e., less than metastatic disease).

4) To determine the pattern of relapsing disease in each treatment arm and in subgroups of patients determined by histology and response to FOMi/CAP.

5) To determine if prophylactic brain irradiation will decrease the chances for brain metastases and influence toxicity or survival.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8309 Status: Ongoing

Title: Autologous Marrow Transplantation for the Treatment of Non-Hodgkin's Lymphoma, Phase II.

Start Date FY 1988	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): To determine the therapeutic potential of high-dose cyclophosphamide and total body irradiation followed by autologous marrow transplantation (AMT) in patients with an otherwise poor prognosis for cure in the specific lymphoma disease categories.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8312 Status: Ongoing

Title: Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in Combination as Second-Line Endocrine therapy of Estrogen Receptor Positive Metastatic Breast Cancer, Phase III.

Start Date FY 1984	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To determine whether combination hormonal therapy with Aminoglutethimide and Hydrocortisone (AH) plus Megestrol Acetate (M), agents thought to have different mechanisms of action, offers an improved response rate with prolonged response duration and increased patient survival over the sequential use of each agent in Estrogen Receptor (ER) positive patients who have progressed after responding to primary hormonal treatment with tamoxifen.

2) To assess the relative toxicities of Megestrol Acetate and medical adrenalectomy.

3) To assess the value of progesterone receptor (PgR) in predicting subsequent responses to a variety of hormonal therapies.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8313 Status: Ongoing

Title: Multiple Drug Adjuvant Chemotherapy for Patients with ER Negative Stage II Carcinoma of Breast, Phase III.

Start Date FY 1984	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 7

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare through a randomized prospective study, the recurrence rates and disease-free intervals (DFI) for postoperative axillary node positive estrogen receptor negative (ER-) breast cancer patients given adjuvant therapy with either short term intense chemotherapy (FAC-M) or one year standard chemotherapy (CMFVP).

2) To compare the effect of these two adjuvant therapies on survival.

3) To compare the relative toxicity of the two therapies.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Five hundred-forty patients have now been accrued to this study. There have been no changes in the toxicity profile. We will revise the accrual goal to 600 patients, which should be reached within the next six months. At that time, the study will be closed and the replacement study activated.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8325 Status: Completed

Title: Combination Chemotherapy with Mitotane (O,P'-DDD) and Cis-Platinum in Metastatic Adrenal Carcinoma, Phase II.

Start Date FY 1984	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Adrenal carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To study the responsiveness of adrenocortical carcinoma to combination chemotherapy consisting of Cis-Platinum (DDP) and Mitotane (O,P'DDD).

2) To study the prognostic features of patients with metastatic and/or unresectable adrenal carcinoma receiving chemotherapy.

3) To document the toxicity of chemotherapy in this group of patients.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is now closed, further information pending final assessment of data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8326/27 Status: Ongoing

Title: Evaluation of Combination Chemotherapy Using High Dose Ara-C in Adult Acute Leukemia and Chronic Granylocytic Leukemia in Blastic Crisis, Phase III.

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, adult acute Leukemia, chronic granulocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the effectiveness of three different drug combinations using high dose Ara-C alone or high dose Ara-C in combination with m-AMSA or Mitoxantrone for remission induction in relapsed adult leukemias including both acute non-lymphocytic leukemia, chronic granulocytic during accelerated or blastic phase, as well as untreated secondary acute leukemias.

2) To monitor the side effects of the above combination chemotherapy schedules.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: As of April, 1989, 321 patients have been entered with 257 being eligible. A total of ten patients are ineligible. Ten patients are not evaluable. There are 44 patients with insufficient information yet available for analysis. A careful analysis relating to the early death rate demonstrates that sepsis was the most frequent cause of early death accounting for 46% of the early deaths. As previously stated, the arm involving high-dose cytosine arabinoside and amsacrine has been closed to patient entry because of the marked increase in the number of early deaths on that arm. Patient accrual continues. the toxicity appears to be reasonable at the present time for patients receiving high-dose cytosine arabinoside alone or high-dose cytosine arabinoside plus Mitoxantrone.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8369 Status: Completed

Title: Combination Chemotherapy with Mitoxantrone, Cis-Platinum and MGBG for Refractory Lymphoma, Phase II.

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To determine if the combination of Mitoxantrone, Cis-Platinum and Methyl-Glyoxal Bis-Guanylhydrazone (MGBG) has reasonable activity (response rate >30%) in patients with refractory unfavorable histology non-Hodgkin's lymphoma. Response duration will also be assessed.

2) To determine the toxicities of this combination of drugs.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is now closed, further information pending final assessment of data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8393 Status: Ongoing

Title: MEL 82 323, National Intergroup Protocol for Intermediate Thickness Melanoma.

Start Date FY 1984	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Melanoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To determine the safest excision margins around the primary melanoma.

2) To evaluate the management of the regional lymph nodes (immediate vs delayed lymphadenectomy).

3) To evaluate the relative prognostic value of various histopathological parameters of melanoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: The Southwest Oncology Group has contributed 73 patients out of approximately 600 patients entered. The median follow-up is approximately 30 months. Local recurrence rates for both the 2 cm. and 4 cm. arms is approximately 3%. Dr. Jewell reported that this study may not be able to determine an advantage of the 2 versus 4 cm. margin given the small recurrence rate. A plea was made at the meeting to enter additional patients, as approximately 100 patients are still needed before the study will close.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8406 Status: Ongoing

Title: Evaluation of Esorubicin (4' Deoxydoxorubicin) in Malignant Lymphoma, Phase II.

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma, malignant	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To determine the response rate and response duration of malignant lymphoma treated with Esorubicin.

2) To define the qualitative and quantitative toxicities of Esorubicin administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8412 Status: Completed

Title: Carboplatin/Cyclophosphamide vs. Cisplatin/Cyclophosphamide in Patients with Measurable, and Non-Measurable (Sub-Optimal) Disease Stages III and IV Ovarian Cancer, Phase III.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Ovarian	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To carry out a Phase III randomized trial of carboplatin + cyclophosphamide and cisplatin + cyclophosphamide in patients with previously untreated measurable and non-measurable (suboptimal) Stage III and IV ovarian cancer to evaluate comparative pathologically proven complete response rates associated with both treatments.

2) To evaluate the comparative toxicities of the two combination drug regimens.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is now closed, further information pending final assessment of data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8417 Status: Ongoing

Title: Evaluation of two Consolidation Regimens in the Treatment of Adult Acute Lymphoblastic Leukemia, Phase III

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Adult acute lymphoblastic leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the effects on remission duration and survival of two consolidation regimens: the L10-M consolidation used in SWOG 8001 versus a regimen employing Daunomycin, Cytosine Arabinoside, 6-Thioguanine and escalating Methotrexate/L-Asparaginase in patients with adult acute lymphoblastic leukemia.

2) To compare the toxicities of the two consolidation regimens.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Accrual to this study has been excellent. The regimen appears to be very well tolerated and leukemic cell samples are being appropriately received by the central reference laboratory at the University of Texas at San Antonio.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8500 Status: Ongoing

Title: Second-Line Treatment of Advanced Measurable Ovarian Cancer with CHIP, Phase II

Start Date FY 1988	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Ovarian	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) to evaluate the antitumor response to CHIP in patients with metastatic or recurrent epithelial carcinoma of the ovary who have failed first-line cisplatin or carboplatin-containing therapy.

2) To further characterize the toxicity of the cisplatin analogue CHIP.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study remains open only to patients who have progressed on cisplatin therapy.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8501 Status: Ongoing

Title: Intraperitoneal Cis-Platinum/Intravenous Cyclophosphamide in Patients with Non-Measurable (Optimal) Disease Stage III Ovarian Cancer, Phase III Intergroup.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Ovarian	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To carry out a Phase III randomized trial of intermediate dose intraperitoneal cis-platinum (100 mg/M^2) plus intravenous cyclophosphamide versus intermediate dose intravenous cis-platinum (100mg/M^2) plus intravenous cyclophosphamide for optimal Stage III ovarian cancer.

2) To evaluate the toxicities and complications of the two combination drug regimens.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available for this study.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8507 Status: Ongoing

Title: Maintenance versus no Maintenance Bcg Immunotherapy of Superficial Bladder Cancer, Phase III

Start Date FY 1986	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Bladder cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 12

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the effectiveness of intravesical and percutaneous BCG immunotherapy given on a maintenance versus a no maintenance schedule with respect to disease free interval and rate of tumor recurrence in patients with transitional cell carcinoma of the bladder.

2) To assess the toxicity of maintenance and no maintenance BCG immunotherapy.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8509 Status: Ongoing

Title: Evaluation of Menogaril in Adenocarcinoma of the Prostate, Phase II

Start Date FY 1986	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Adenocarcinoma, prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 8

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To assess the antitumor activity of menogaril in patients with advanced adenocarcinoma of the prostate.

2) To define the qualitative and quantitative toxicities of menogaril administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual. However, it will remain open for followup purposes.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8510 Status: Completed

Title: Intra-Arterial Cis-Platinum and Radiation Therapy in Primary Brain Tumors: A Phase Randomized Study Comparing Sequential and Combined Treatments.

Start Date FY 1986	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Brain tumors	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To assess the toxicity and response to therapy of intra-arterial Cis-platinum administered in two schedules, sequential and concomitant with radiation therapy in the treatment of patients with primary malignant gliomas.

2) To determine the time to progression and overall survival in patients with malignant gliomas treated with intra-arterial Cis-platinum in addition to radiation therapy.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is now closed, further information pending final assessment of data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8514 Status: Completed

Title: Randomized Comparison of Cisplatin + 5-Fluorouracil vs CBDCA + 5-Fluorouracil vs Methotrexate in Advanced Squamous Cell Carcinoma of the Head and Neck, Phase III.

Start Date FY 1986	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, squamous cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To determine and compare the response rate (complete and partial), duration of response and survival time of patients treated with two combination chemotherapy regimens: (Arm I) Cisplatin + 5-fluorouracil, (Arm II) CBDCA + 5-fluorouracil with (Arm III) single agent methotrexate.

2) To determine the toxicities associated with each of the three treatments.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is now closed, further information pending final assessment of data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8515 Status: Ongoing
Title: Evaluation of Menogaril in Non-Hodgkins Lymphoma, Phase II.

Start Date 13 May 1988	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Non-Hodgkins, Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1
Total Number of Subjects Enrolled to Date: 2
Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To determine the response rate and response duration for favorable and unfavorable histology Non-Hodgkin's lymphoma (NHL) treated with Menogaril.

2) To define the qualitative and quantitative toxicities of Menogaril administered in a phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of non-Hodgkin's lymphoma with at least one site of bidimensionally measurable disease. Patients must have failed and recovered from potentially curable treatment. Patients with a cumulative dose of Adriamycin $\geq$ 250 mg/m^2 are not eligible for this study. allowable prior chemotherapy depends on disease type. Patients will be stratified according to histology: unfavorable histology NHL vs favorable histology NHL.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been 30 patients registered to this study so far. They are approximately evenly balanced between favorable and unfavorable histologies. There are no major problems. No unexpected toxicity has been seen.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8516 Status: Ongoing

Title: A Phase III Comparison of CHOP vs m-BACOD vs ProMACE-CytaBom vs MACOP-B in Patients with Intermediate or High-Grade Non-Hodgkin's Lymphoma.

Start Date FY 1986	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Non-Hodgkin's lymphoma, high-grade	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 9

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare in a randomized Group-wide setting the complete response rate, response duration and survival of patients with intermediate and high-grade non-Hodgkin's lymphoma treated with one of four combination chemotherapy regiments: CHOP, m-BACOD, ProMACE-CytaBOM, or MACOP-B.

2) To compare the toxicities of each regimen in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Five hundred and sixty-one patients have now been randomized to this study. Accrual averages approximately 20-28 cases per month. There is a reasonable balance between the stratification factors. The primary reason for ineligibility involves the failure to confirm pathologic diagnosis at review; 59 patients are ineligible. No unusual toxicities were observed. Every patient randomized to a given arm should continue treatment on that arm unless there is a medical contraindication, as the results of treatments in these patients must be analyzed whether they are subsequently deemed eligible or ineligible.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8518 Status: Completed

Title: Study of Combined Modality Treatment for Inoperable Squamous Cell Carcinoma of the Esophagus, Phase I-II.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, squamous cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To determine the efficacy and toxicity of 5-fluorouracil (5-FU) and Cis-Platinum combined with concurrent radiotherapy in patients with Stage III epidermoid carcinoma of the esophagus.

2) To determine the feasibility and toxicity of "up-front" palliative laser therapy with this regiment.

3) To estimate the response rate and duration of response by clinical and computed tomography staging.

4) To determine the survival of patients treated by these modalities.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is now closed, further information pending final assessment of data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8519 Status: Completed

Title: Phase II Evaluation of Methyl-Glyoxal Bis-Guanylhydrazone (MGBG) Patients With Advanced Bladder Cancer.

Start Date FY 1986	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, bladder	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To determine response rate and remission duration with weekly intravenous therapy using MGBG in patients with metastatic bladder carcinoma who have failed on higher priority protocols.

2) To define the qualitative and quantitative toxicity of this regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is now closed, further information pending final assessment of data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8520 Status: Ongoing

Title: Cis-Diamminedichloroplatinum II: Methotrexate and Bleomycin in the Treatment of Advanced Epidermoid Carcinoma of the Penis, Phase II.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, epidermoid	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To determine the response rate in patients with advanced epidermoid carcinoma of the penis treated with cis-platinum, methotrexate, and bleomycin.

2) To evaluate the toxicity of this three-drug combination.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Nearly one-half of projected patients are accrued.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8530 Status: Ongoing

Title: Efficacy of Prednisone in Refractory and Relapsing Multiple Myeloma and Glucocorticoid Receptors, Phase II.

Start Date 7 Nov 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Myeloma, multiple	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To estimate the response rate and duration with high dose prednisone in patients with refractory myeloma.

2) To measure glucocorticoid receptors in multiple myeloma.

Technical Approach: All patients must have a histologic diagnosis of multiple myeloma. Eligible patients must have had prior chemotherapy or hormonal therapy for myeloma and progression of disease.

Therapy will follow the schema outlined in the study protocol.

Progress: One hundred and eight patients have now been registered. There has been a correlation between glucocorticoid receptor expression with response to alternate day prednisone and survival in 77 patients. To date, objective response to prednisone has only been seen in 10% of the patients entered on study. This best results have been in patients who have had intermediate (as opposed to high or low) receptor levels expressed.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8568 Status: Ongoing

Title: Combined Modality Therapy for Advanced Stage III Breast Cancer (T3b any N, T3aN2-3, or any T4).

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast cancer, stage III	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To evaluate by serial biopsy and flow cytometry whether or not an increase of the percentage of cells in $S+G_2+M$ can be induced in patients with locally advanced breast cancer by synchronization with a high physiologic dose of estradiol before chemotherapy is applied.

2) To obtain information by flow cytometry and serial biopsy when this increase in $S+G_2+M$ occurs.

3) To evaluate the toxicity of an aggressive program of hormonal synchronization, chemotherapy, radiation therapy and surgery on patients with T3b any N, T3aN2-3, T3aN, or T4 breast cancer lesions.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Twenty-nine patients have now been registered on this study. The majority of the patients entered are estrogen receptor positive; of those, most have had a slight increase in their S-phase and G2+M phase by flow cytometry with estrogen priming. However, the magnitude of the increase is not great. Several more patients need to be accrued before this study will close. A replacement study is being prepared using tamoxifen block followed by estrogen synchronization. There has been no unusual toxicity from the estrogen priming.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8573 Status: Ongoing

Title: Treatment of Limited Small Cell Cancer with Concurrent Chemotherapy Radiotherapy and Intensification with High Dose Cyclophosphamide.

Start Date FY 1986	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, small cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 6

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To estimate the response rate and survival of patients with limited small cell lung cancer when treated with concurrent chemo-radiotherapy followed by chemotherapy and late intensification with high dose cyclophosphamide.

2) To assess the toxicity of this treatment program.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8590 Status: Ongoing

Title: Phase III Study to Determine the Effect of Combining Chemotherapy With Surgery and Radiotherapy for Resectable Squamous Cell Carcinoma of the Head and Neck.

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Squamous cell carcinoma of head and neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 6

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To test whether the addition of chemotherapy to surgery and radiotherapy prolongs disease-free survival and survival between the two study groups.

2) To test whether the addition of chemotherapy to surgery and radiotherapy increases local control rates at the primary site and/or the cervical neck nodes.

3) To determine if the patterns of failure have been changed with the addition of chemotherapy.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: The studies are accruing well and will be closed this summer. No analysis to date has been done, except to note that somewhere between 30 to 40 percent of the patients have not been able to go on study, primarily due to the presence of positive margins after surgery.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8591 Status: Ongoing

Title: NCI Intergroup #0035, An Evaluation of Levamisole Alone or Levamisole plus 5-Fluorouracil as Surgical Adjuvant Treatment for Resectable Adenocarcinoma of the Colon.

Start Date FY 1985	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Adenocarcinoma of colon	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 15

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): To assess the effectiveness of levamisole alone and levamisole plus 5-fluorouracil as surgical adjuvant regimens for resectable colon cancer by comparison with untreated controls.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8594 Status: Ongoing

Title: A Phase III Trial of Cis-Platin Alone or in Combination with Doxorubicin, Vinblastine, and Methotrexate in Advanced Bladder Cancer.

Start Date FY 1986	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, bladder	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): To determine if cisplatin in combination with doxorubicin, vinblastine and methotrexate is more effective than cisplatin alone in the treatment of patients with advanced bladder cancer in terms of objective response rate, response duration and survival.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8598 Status: Ongoing

Title: Prospective Trial for Localized Cancer of the Esophagus: Comparing Radiation as a Single Modality to the Combination of Radiation Therapy and Chemotherapy, Phase III Intergroup.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, esophagus	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To determine the role of chemotherapy for a potentially curable subset of patients with squamous cell cancer of the esophagus.

2) To determine if the patters of recurrence for patients treated with the combination of chemotherapy and radiation differs from those patients treated with radiation alone.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8600 Status: Ongoing

Title: A Randomized Investigation of High Dose versus Standard Dose Cytosine Arabinoside With Daunorubicin in Patients With Acute Non-Lymphocytic Leukemia, Phase III.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, acute, non-lymphocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare, among patients with acute non-lymphocytic leukemia, the rate of complete remission produced by induction regimens of either standard dose Cytosine Arabinoside and Daunorubicin or high-dose Cytosine Arabinoside and Daunorubicin.

2) To compare the durations of complete remission and of disease-free survival among patients who each receive one of three combinations of induction and consolidation regimens.

3) To determine the comparative toxicities of these three programs of induction and consolidation.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Accrual to this study continues at the same rate. A reminder that the dose of high-dose cytosine arabinoside for all patients was reduced to 2 grams/m^2 regardless of age. This dose modification was made because of significant neurotoxicity in patients receiving the high-dose cytosine arabinoside arm.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8608 Status: Ongoing

Title: Mitoxantrone Plus Cis-Platinum in Patients With Advanced Breast Cancer, Phase I-II.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To evaluate the response rate and remission duration of the combination of Mitoxantrone and cis-platinum used as second-line therapy for metastatic breast cancer.

2) To evaluate the toxicity of this drug combination in these patients.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This trial has 26 patients entered and there is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8610 Status: Ongoing

Title: Prospective Randomized Clinical Trial of the Capillary Cloning System for Patients with Extensive Small-Cell Lung Cancer, Phase III.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer Small-Cell Lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Ongoing

Objective(s): 1) To evaluate the ability of the capillary cloning system to improve upon patient response and survival when compared to a standard regimen (Vincristine + adriamycin + cyclo-phosphamide)(VAC) by selecting patient-specific regimens. These individual patient regimens will be formulated from the best two or three drugs which are effective against the patient's small-cell lung cancer in vitro.

2) To assess whether a cloning system has a place in the clinical care of the patient with extensive small-cell lung cancer.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8611 Status: Completed

Title: A Randomized Trial of Two Schedules of Trimetrexate Versus 5-Fluorouracil in Colorectal Carcinoma, Phase II-III.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, colorectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To determine and compare the response rates, response durations and toxicities of trimetrexate given on two different schedules to patients with advanced colorectal cancer.

2) To compare patient survival on trimetrexate with those on 5-FU alone.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is now closed, further information pending final assessment of data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8616 Status: Ongoing

Title: Intergroup Phase III Randomized Study of Doxorubicin and Dacarbazine With and Without Ifosfamide and Mesna in Advanced Soft Tissue and Bone Sarcoma.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Sarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): *To determine if the addition of ifosfamide to doxorubicin and* dacarbazine significantly changes the response rate, survival, and toxicity.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: As of April 1, 1989, 387 patients had been registered on the study. Thirty-nine of these patients were in the non-randomized arm for metastatic osteogenic sarcoma, Ewing's sarcoma and rhabdomyosarcoma. This left 348 registered to the randomized portion of the study. Since the original goal of the randomized part of the study was to accrue 280 response evaluable patients, the accrual goal had been met for this portion of the study and it was closed. The non-randomized portion of the study will remain open in an attempt to determine the response rate of osteosarcoma, Ewing's sarcoma, and rhabdomyosarcoma to combination therapy with doxorubicin, DTIC, and ifosfamide.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8621 Status: Ongoing

Title: Chemo-Hormonal Therapy of Postmenopausal Receptor-Positive Breast Cancer, Phase III.

Start Date 15 Jul 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare initial combined chemo-hormonal therapy with initial hormonal therapy with respect to survival.

2) To compare initial chemo-hormonal therapy using tamoxifen with that using DES with respect to survival.

3) A secondary goal is to compare combined chemo-hormonal therapy with initial hormonal therapy with respect to response in patients with measurable disease.

Technical Approach: Patients must have clinical or histologic confirmation of recurrent or disseminated breast cancer, with tumor positive for estrogen receptor or progesterone receptor. Patients with completely dissected disease or with a life threatening visceral disease will be ineligible.

Therapy will follow the schema outlined in the study protocol.

Progress: To early for any reportable data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8624 Status: Completed

Title: A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Myeloma, multiple	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To compare the effectiveness of three chemotherapy induction schedules for the induction of remission in previously untreated patients with multiple myeloma. The three schedules are: 1) VMCP/VBAP; 2) VAD; 3) VMCPP/VBAPP.

2) To compare the value of Intron-A maintenance versus no maintenance for patients proven to achieve remission.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is now closed, further information pending final assessment of data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8626 Status: Ongoing

Title: Study of Recombinant DNA Gamma Interferon in Advanced Cancer of the Pancreas, Phase II.

Start Date FY 1988	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, pancreatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 7

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To determine the clinical response of recombinant gamma interferon in pancreatic adenocarcinoma.

2) To define the qualitative and quantitative toxicities of recombinant gamma interferon in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8629 Status: Completed

Title: Adjuvant Therapy With Adriamycin Plus Cisplatin for Endometrial Sarcomas at High Risk of Recurrence, Phase II.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Sarcoma, endometrial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To examine the effect of adjuvant systemic chemotherapy on survival and pattern of recurrence in patients with limited endometrial sarcoma.

2) To determine the toxicities of the adjuvant systemic chemotherapy in patients with limited endometrial sarcoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is now closed, further information pending final assessment of data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8630 Status: Completed

Title: Phase II Study of Recombinant DNA Gamma Interferon in Advanced Colorectal Cancer.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, colorectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To determine the clinical response rate of recombinant gamma interferon in colorectal cancer.

2) To define the qualitative and quantitative toxicities of recombinant gamma interferon in colorectal cancer.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is now closed, further information pending final assessment of data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8632 Status: Completed
Title: Evaluation of Echinomycin in Central Nervous System Tumors, Phase II.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Tumors, central nervous system	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0
Total Number of Subjects Enrolled to Date: 1
Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To assess the efficacy of Echinomycin given once every seven days times four weeks followed by a two-week rest in recurrent or residual central nervous system tumors by evaluation of response--rate, duration and survival.

2) To assess the qualitative and quantitative toxicities of Echinomycin given by this schedule in a Phase II setting.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is now closed, further information pending final assessment of data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8640 Status: Completed

Title: Evaluation of Didemnin B or Trimetrexate in the Treatment of Metastatic or Recurrent Squamous Carcinoma of the Uterine Cervix.

Start Date 15 Dec 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Carcinoma, Cervix	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): To evaluate tumor response to didemnin-B or trimetrexate in patients with metastatic or recurrent squamous carcinoma of the uterine cervix who have failed treatment protocols of higher priority.

Technical Approach: This study is open to patients who have histologically proven metastatic or recurrent squamous carcinoma of the uterine cervix. The patients must have bidimensionally measurable disease. The patients may have no detectable ascites or pleural fluid. There may be no prior systemic chemotherapy and any prior radiotherapy must have been to less than 25% of the bone marrow.

Therapy will follow the schema outlined in the study protocol.

Progress: Study analysis is underway. However, there is still no reportable data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8641 Status: Completed

Title: Phase II Trial of Ifosfamide and Cisplatin for Advanced Measurable Sarcomas.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Sarcomas, advanced measurable	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To evaluate the response-rate and duration of response of advanced soft-tissue sarcomas treated with the combination of ifosfamide and high-dose cisplatin.

2) To evaluate the qualitative and quantitative toxicities of the combination of ifosfamide and high-dose cisplatin in a population of patients with advanced soft-tissue sarcomas.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8642 Status: Ongoing

Title: Recombinant Human Interferon-Gamma for the Adjuvant Treatment of High Risk Malignant Melanoma After Surgical Excision of the Primary Lesion.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Melanoma, malignant	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the overall survival and of disease-free survival among patients who are at high risk for recurrence of melanoma following surgical resection of all known disease, and who are randomized to receive either recombinant human interferon-gamma adjuvant therapy or no adjuvant therapy.

2) To estimate the rates of toxicities among the patients who receive recombinant human interferon-gamma as adjuvant therapy.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study has accrued very rapidly. There are currently 195 patients registered. There has been excellent compliance and very minimal side effects. Statistical requirements for this study and, in view of the rapid accrual, increase the power to 90%. This will require more patients. The initial protocol expectations were approximately 230 patients with a power of 80. An increase in the power to 90 will require accrual in excess of 300 patients.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8691 Status: Ongoing

Title: A Randomized Comparison of Deoxycoformycin versus Alpha-Interferon in Previously Untreated Patients With Hairy Cell Leukemia.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, hairy cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare Deoxycoformycin and Alpha-interferon with respect to frequency of response, time to response and duration of relapse-free survival among unsplenectomized patients with hairy cell leukemia.

2) To compare Deoxycoformycin and Alpha-interferon with respect to improvement in specific patient characteristics.

3) To estimate the rate of response for each treatment when used among patients who have failed to respond to or had unresolvable toxicity from the other treatment.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This important study continues to accrue at a rate exceeding the anticipated accrual goal. It is anticipated that this study will be ready for closure in the summer of 1989.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8692 Status: Ongoing

Title: Therapy in Premenopausal Women with advanced, ER Positive or PgR Positive Breast Cancer: Surgical Oophorectomy vs. the LH-RH Analog, Zoladex: Phase III, Intergroup.

Start Date 14 Oct 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the time to treatment failure and survival of medical castration using Zoladex with surgical castration in premenopausal women with advanced, ER + or PgR + breast cancer.

2) To compare the response rate of the two treatments.

3) To assess the response rate to surgical castration in patients failing to respond to or relapsing on Zoladex, and the response rate to Zoladex in patients failing to respond to or relapsing on surgical castration.

4) To compare toxicities of medical castration and surgical castration.

5) To assess the value of post-treatment hormone levels (LH, FSH and estradiol) in predicting response to medical castration.

6) To assess the effect of long-term Zoladex treatment on hormone levels (LH, FSH and estradiol) in responding patients.

Technical Approach: Patients must have metastatic breast cancer. They must be premenopausal, have a performance status of 0-2 and be ER or PgR positive. No prior hormone therapy or chemotherapy for advanced disease is allowed. Prior adjuvant chemotherapy is allowed. Adjuvant tamoxifen is allowed provided relapse occurred $\geq$ 6 months after completion of therapy. Therapy will follow the schema outlined in the study protocol.

Progress: Only 31 patients have been entered onto this study. If accrual does not pick up we will revise this into a second-line study following tamoxifen therapy in premenopausal metastatic breast cancer.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8693 Status: Ongoing

Title: Adjuvant Therapy of Primary Osteosarcoma: A Phase III Randomized Intergroup Study.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Osteosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To determine whether the intensity of adjuvant chemotherapy affects its success in terms of local recurrence, disease-free survival and overall survival in patients who have primary osteosarcoma of the extremities and who are randomized to either surgery followed by adjuvant chemotherapy with three drugs or surgery followed by adjuvant chemotherapy with six drugs.

2) To determine the influence of clinical prognostic variables on disease outcome.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study was temporarily closed because of severe toxicity reported on two patients treated according to the protocol, but not registered on the protocol. An amendment in the treatment regimen has been prepared in an attempt to lessen the risk of severe mucositis as was seen in those patients treated off the protocol. In addition, the protocol has been amended to reflect that the Statistical Center has changed from ECOG to the Southwest Oncology Group. A revised protocol is to be sent to Group members in the near future.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8694 Status: Ongoing

Title: A comparison of Pentostatin and Alpha-Interferon in Splenectomized Patients With Active Hairy Cell Leukemia.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, hairy cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the frequency of response between pentostatin and a-IFN treatment in patients with hairy cell leukemia who following splenectomy manifest active or progressive disease.

2) To compare time to response between these two treatments.

3) To compare the response duration between these two treatments.

4) To determine whether pentostatin salvages non-responders to a-IFN treatment and whether a-IFN salvages non-responders to pentostatin treatment.

5) To compare the toxicity of the two treatments.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study will continue to have problems with accrual as many of the patients with hairy cell leukemia are no longer being splenectomized. This change in therapeutic approach decreases the number of patients who will be potentially available for registration on this study. We will continue to register patients on this trial as it is an important intergroup effort.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8695 Status: Ongoing

Title: (GOG 85) A Randomized Comparison of Hydroxyurea versus 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy in Patients with Stage II-B, III, and IV-A Carcinoma of the Cervix and Negative Para-aortic Nodes.

Start Date FY 87	Est Comp Date:
Principal Investigator:(vice Burke) Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Cervix	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To determine whether hydroxyurea or the combination of 5-Fluorouracil and cisplatin is superior as a potentiator of radiation therapy in advanced cervical carcinoma.

2) To determine the relative toxicities of hydroxyurea versus the combination of 5-fluorouracil and cisplatin when given concurrently with radiation therapy.

Technical Approach: Patients with primary, previously untreated, histologically confirmed invasive squamous cell carcinoma, adenocarcinoma or adenosquamous carcinoma of the uterine cervix, Stages II-B, III-A, III-B and IV-A with negative para-aortic nodes are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This intergroup study has accrued patients very slowly from the Southwest Oncology Group because of the requirement for surgical staging eligibility. There is no further reportable data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8696 Status: Completed

Title: Prediction of Recurrence and Therapy Response in the Node Negative Breast Cancer Patient by DNA Flow Cytometry.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To correlate the proliferative activity, ploidy, and HER-2/new gene expression with clinical features including the response to therapy and survival in patients entered on SWOG 8294.

Technical Approach: Previously obtained tissue specimens from patients enrolled on SWOG 8294 are sent for flow cytometry analysis.

There is no therapy involved in this study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8697 Status: Ongoing

Title: Phase III Combination Chemotherapy of Predominantly Hormone Insensitive Metastatic Breast Cancer: An Evaluation of CAF Versus Rotating Regimens of CAF and TSAVBH Induction Therapy Followed by Observation or Maintenance Therapy with CMF(P)TH or CMFH Intergroup.

Start Date FY 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) Investigate the induction efficiency and impact on time to treatment failure and survival of CAF vs CAF-TsAVbH used in a rotating schedule.

2) Investigate the value of CMF(P)TH vs no maintenance treatment in duration of complete response and survival.

3) Evaluate on-study disease characteristics and patient discriminants with respect to their prognostic use of the above objectives.

Technical Approach: Patients must have histologically documented mammary carcinoma with clinical and/or laboratory evidence of metastatic or recurrent disease. Patients must have measurable disease. All patients with ER negative tumors are eligible unless they have responded to prior hormone manipulation therapy. ER positive or ER unknown patients are eligible only if they have had prior therapeutic hormone manipulation and did not respond to this therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8700 Status: Completed

Title: Consolidation Therapy with High-Dose Cyclophosphamide and Total Body Irradiation, Followed by Autologous Marrow Infusion in Metastatic Breast Cancer, Phase II.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To assess the effect of high-dose cyclophosphamide and total body irradiation with autologous bone marrow support on the response quality after "standard" chemotherapy.

2) To assess the survival after consolidation with high-dose cyclophosphamide and total body irradiation with autologous bone marrow support.

Technical Approach: Patients must have metastatic breast carcinoma in partial or complete remission after no more the six cycles of an combination chemotherapy. Partial and complete responses must have been maintained for at least four weeks. ER + patients are eligible only if they have failed hormonal therapy of have liver or lymphangitic pulmonary disease.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8703 Status: Completed

Title: Evaluation of Vinblastine and High-dose Cis-Platinum in the Treatment of Advanced Non-Small Cell Lung Carcinoma, Phase II.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Carcinoma, Lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To obtain an estimate of the activity of combination chemotherapy with vinblastine and high dose cisplatin in the treatment of advanced non-small cell lung carcinoma.

2) To assess the toxicity of combination chemotherapy with vinblastine and high dose cisplatin in patients with advanced non-small cell lung carcinoma.

Technical Approach: Patients with extensive non-small cell carcinoma of the lung who have recurrent or metastatic disease post surgery or radiation are eligible for this study. Patients must have adequate renal function, no prior chemotherapy and no history of brain metastasis.

Therapy will follow the schema outlined in the study protocol.

Progress: This trial of high-dose cisplatin and vinblastine in Stage IV NSCLC has accrued 54 registrations, and was temporarily closed on 11/15/88 as having met its accrual objectives. Dr. Grunberg reported that at least 45 patients had received a full initial course of therapy, and recommended that the trial be permanently closed.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8710 Status: Ongoing

Title: Trial of Cystectomy Alone Versus Neoadjuvant M-VAC + Cystectomy in Patients with Locally Advanced Bladder Cancer, Phase III.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian Thompson, MAJ, MC
Key Words: Cancer, Advanced Bladder	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the survival of those patients with locally advanced bladder cancer treated with cystectomy alone to those treated with M-VAC followed by cystectomy in a randomized Phase III neoadjuvant trial.

2) To quantify the "tumor downstaging" effect of neoadjuvant M-VAC in patients with locally advanced bladder cancer.

Technical Approach: All patients must have histologically proven diagnosis of T_2-T_{4a}, N_0, M_0 transitional cell carcinoma of the bladder without mixed histology. All patients must have adequate kidney, liver, and bone marrow function, a performance status of 0-1, and be judged potentially curable.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has a total of 55 patients registered as of 3/89. No inordinately severe toxicities have been reported.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8711 Status: Ongoing
Title: A Study of Reproductive Function in Patients with Testicular Cancer.

Start Date FY 88	Est Comp Date:
Principal Investigator:	Facility:
Timothy J. O'Rourke, LTC, MC	Brooke Army Medical Center
Dept/Svc:	Associate Investigators:
Department of Medicine/Oncology	Richard O. Giudice, MAJ, MC
Key Words:	
Cancer, Testicular	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1
Total Number of Subjects Enrolled to Date: 1
Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1. To evaluate the natural history of seminal fluid and hormonal parameters noted in Stage A testicular cancer patients treated by orchiectomy alone.

2. To evaluate the effects of a) orchiectomy plus platinum based combination chemotherapy or radiation therapy and b) retroperitoneal node dissection on the seminal fluid and hormonal parameters of Stage A, B, or C testicular cancer patients.

3. To estimate the median time to return to ejaculatory function following orchiectomy and retroperitoneal node dissection.

4. To study the effect of testicular cancer on sexual/ reproductive functioning.

Technical Approach: Each patient must have histologically proven diagnosis of testis cancer for which he has undergone an orchiectomy. Patients must be registered within three weeks of their surgery.

Therapy will follow the schema outlined in the study protocol.

Progress: There has been one registration to this study. There is no reportable groupwide data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8712 Status: Completed
Title: A Phase II Trial of Trimetrexate in the Treatment of Hepatoma.

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Hepatoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0
Total Number of Subjects Enrolled to Date: 0
Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): To determine the response rate, response duration and toxicity of trimetrexate given on a daily times five schedule every three weeks to patients with hepatoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is now closed, further information pending final assessment of data.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8714 Status: Ongoing
Title: Evaluation of Amonafide in Colorectal Carcinoma, Phase II.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Carcinoma, Colorectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0
Total Number of Subjects Enrolled to Date: 3
Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To evaluate response to amonafide in previously untreated patients with colorectal carcinoma.

2) To assess the qualitative and quantitative toxicities of amonafide.

Technical Approach: Patients must have biopsy proven bidimensionally measurable adenocarcinoma arising from the colon or rectum. Patients may have had previous surgical therapy or previous radiation therapy. Patients must not have received any prior chemotherapy or no more than one prior biologic regimen.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8715 Status: Completed
Title: Evaluation of Amonafide in Advanced Sarcomas.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Sarcomas, Advanced	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1
Total Number of Subjects Enrolled to Date: 1
Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To evaluate the response rate of advanced sarcomas treated with amonafide.

2) To assess the qualitative and quantitative toxicities of amonafide in a Phase II study.

Technical Approach: Patients must have measurable, pathologically verified, advanced soft tissue sarcoma. Patients may not have mesothelioma, Kaposi's sarcoma or osteogenic sarcoma. Prior treatment is allowed if no more than one prior chemotherapeutic regimen for metastatic disease has been given.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has reached the accrual goal and is now in the process of review.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8717 Status: Ongoing

Title: Evaluation of Amonafide and Didemnin-B in the Treatment of Ovarian Cancer.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Ovarian	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To conduct a randomized Phase II trial of two treatment regimens, amonafide and Didemnin-B and to evaluate tumor response to each of these agents in patients with metastatic or recurrent epithelial carcinoma of the ovary who have failed on higher priority treatment protocols.

2) To assess the qualitative and quantitative toxicities of each of these treatment regimens.

Technical Approach: Patients must have histologically proven incurable advanced metastatic or recurrent epithelial Stage III or IV carcinoma of the ovary. Patnology review is required to verify eligibility. Patients must have bidimensionally measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8719 Status: Ongoing

Title: Evaluations of Didemnin B or Ifosfamide/Mesna in Endocrine Resistant Prostate Cancer and of Ifosfamide/Mesna in Patients without Prior Endocrine Manipulation. Phase II

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): To determine the response rate, response duration and toxicity of trimetrexate given on a daily x 5 schedule every three weeks to patients with hepatoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8720 Status: Ongoing

Title: Evaluation of Amonafide in Pancreatic Adenocarcinoma

Start Date 9 Sep 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Pancreatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To evaluate response to amonafide in patients with pancreatic adenocarcinoma.

2) To assess the qualitative and quantitative toxicities of amonafide.

Technical Approach: Patients must have a verified diagnosis of pancreatic adenocarcinoma. Patients must have objectively measurable lesion(s) excluding CNS metastases. Prior chemotherapy is not permitted and only one prior biologic regimen.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8721 Status: Ongoing

Title: A Phase II Trial of Trimetrexate in the Treatment of Esophageal Cancer.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Esophageal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To determine the response rate, response duration and toxicity of trimetrexate given on a daily x 5 schedule every three weeks to patients with esophageal cancer.

Technical Approach: Patients must have a biopsy proven epidermoid carcinoma that is measurable. Patients may have had previous surgical therapy or radiation therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available for this study.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8723 Status: Ongoing

Title: Evaluation of Amonafide in Disseminated Malignant Melanoma Phase II.

Start Date 9 Sep 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Melanoma, Disseminated	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To evaluate response to amonafide in patients with Disseminated Malignant Melanoma.

2) To assess the qualitative and quantitative toxicities of amonafide.

Technical Approach: Patients must have pathologically verified malignant melanoma. Only patients with Stage IV disease are eligible. Patient must not have received prior chemotherapy and only one prior biologic regimen is permitted.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8725 Status: Ongoing

Title: Evaluation of Amonafide in Cervical Cancer.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Cervical	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To evaluate response to amonafide in patients with metastatic or recurrent epithelial carcinoma of the cervix who have failed on higher priority treatment protocols.

2) To assess the qualitative and quantitative toxicities of amonafide.

Technical Approach:

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8726 Status: Ongoing

Title: Evaluation of Amonafide in Refractory and Relapsing Multiple Myeloma.

Start Date 15 July 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Myeloma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To assess the antitumor activity of amonafide in patients with refractory and relapsing multiple myeloma by estimation of the response rate and the remission duration.

2) To assess the qualitative and quantitative toxicities of amonafide administered in a Phase II study.

Technical Approach: Patient must have a histologic diagnosis of multiple myeloma, have prior exposure to therapy on SWOG 8624 and have failed therapy, or have received only a single prior chemotherapy regimen. Three weeks must have elapsed since prior chemo- or radiotherapy. Patients must be past the nadirs from previous therapy and have a performance status of 2 or better. They must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This study is in the process of review.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8728 Status: Ongoing

Title: Evaluation of Didemnin-B in Metastatic Adenocarcinoma of the Kidney, Phase II.

Start Date 22 Jan 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Kidney, Adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To evaluate the likelihood of response in patients with advanced renal cell carcinoma in order to assess whether Didemnin-B should be advanced to further studies.

2) To evaluate the qualitative and quantitative toxicities of Didemnin-B.

Technical Approach: All patients must have a histologically confirmed diagnosis of advanced adenocarcinoma of the kidney not curable by surgery. Disease must be bidimensionally measurable. All patients must have adequate kidney, liver, and bone marrow function. Patients must have a performance status of 0-2.

Patients may not have received prior chemotherapy. One prior hormonal or immunotherapy is permitted, but objective evidence of progression of disease following prior treatment is needed.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-seven patients were accrued to this study in four months for an accrual rate of 6.7 patients per month. The study is now closed for evaluation of response and toxicity.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8729 Status: Ongoing

Title: A Phase II Trial of Low Dose Pala and High Dose 5-FU as a Short Term Infusion in the Treatment of Adenocarcinoma of the Pancreas.

Start Date 8 Apr 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Pancreas	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To evaluate response to a new regimen consisting of 24-hour infusion of high dose (effector) 5-FU and low dose (modulator) PALA in patients with advanced pancreatic adenocarcinoma.

2) To assess the qualitative and quantitative toxicities of the regimen.

Technical Approach: Patients must have verified advanced pancreatic adenocarcinoma that is objectively measurable.

Patients must have a central venous access placement (Hickman catheter or Infusaport) prior to starting therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was temporarily closed to patient accrual on June 15, 1988 for evaluation of response. There was no evidence of response seen, therefore this study is now undergoing full evaluation.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8731 Status: Completed
Title: Ifosfamide and Mesna in Malignant Mesothelioma, Phase II.

Start Date 13 May 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Malignant Mesothelioma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0
Total Number of Subjects Enrolled to Date: 0
Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To assess the activity of Ifosfamide and the uroprotector 2-mercaptoethane sodium sulphonate (Mesna) in patients with unresectable malignant mesothelioma.

2) To further evaluate the toxicity pattern of continuous infusion Ifosfamide/ Mesna.

Technical Approach: All patients must have a pathologically verified diagnosis of unresectable malignant mesothelioma of the pleura, peritoneum, pericardium, or paratesticular area. All patients must have bidimensionally objectively measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Responses have been seen on this protocol in malignant mesothelioma. Currently 18 patients are registered on the study.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8732 Status: Completed
Title: Evaluation of Amonafide in Endometrial Carcinoma.

Start Date 13 May 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Charles R. Harrison, MAJ, MC Kenneth Hancock, MAJ, MC
Key Words: Carcinoma, Endometrial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0
Total Number of Subjects Enrolled to Date: 0
Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To evaluate response to amonafide in patients with endometrial carcinoma.

2) To assess the qualitative and quantitative toxicities of amonafide.

Technical Approach: Patients must have histologically proven incurable advanced metastatic or recurrent endometrial carcinoma. Disease must be bidimensionally measurable.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8733 Status: Ongoing

Title: Evaluation of Operable Bladder Cancer Patients with Pre-Operative Irradiation + 5-FU Alone, Phase II, a Pilot Study for Patients Ineligible for SWOG-8710.

Start Date 15 Jul 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian Thompson, MAJ, MC
Key Words: Cancer, Bladder	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) Operable Patients: To evaluate the complete downstaging rate in patients with bladder cancer who are treated with pre-operative 5-FU/radiation. to assess the efficacy of treating patients with no histologic evidence of residual tumor following irradiation and 5-FU with additional irradiation and 5-FU without cystectomy. To assess the efficacy of treating patients who are not free of disease after initial treatment with 5-FU/radiation with radical cystectomy.

2) Inoperable Patients: To estimate the response rate of patients treated with 5-FU and radiation. To assess the qualitative and quantitative toxicities of this regimen in the treatment of bladder cancer.

Technical Approach: Patients must have primary or recurrent bladder cancer confined to the pelvis and no evidence of spread beyond the regional lymph nodes at or below the level of the bifurcation of the iliac vessels. Patients must not have any prior pelvic irradiation, or prior malignancies which are active, or synchronous non-bladder malignancies other than basal or squamous cell carcinoma of the skin or any other carcinoma in situ. Patients with prior inactive malignancies are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8734 Status: Completed

Title: A Phase II Trial of Low Dose Pala and High Dose 5-FU as a Short Term Infusion in the Treatment of Adenocarcinoma of the Stomach.

Start Date 13 May 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Stomach	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To evaluate response to a new regimen consisting of 24 hour infusion of high dose (effector) 5-FU and low dose (modulator) PALA in patients with advanced adenocarcinoma of the stomach.

Technical Approach: Patients must have verified advanced gastric adenocarcinoma that is objectively measurable. A central venous access placement is necessary prior to starting the therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8735 Status: Ongoing

Title: A Phase II Study of Recombinant Human Interferon-Alfa and Recombinant Human Interferon-Gamma in Previously Untreated Patients with Chronic Myelogenous Leukemia.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia Myelogenous, Chronic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To develop an appropriate dose for alternate day therapy with recombinant human alfa and gamma interferon, in previously untreated patients with chronic myelogenous leukemia (CML).

2) To estimate whether such a regimen is of sufficient effectiveness and of sufficiently limited toxicity to justify its investigation in further trials. The effectiveness of the regimen will be measured by the rates of hematologic, cytogenetic, and molecular remission it produces.

3) To evaluate effectiveness and toxicity of such a regimen once an appropriate dose is developed.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8736 Status: Ongoing
Title: Treatment of Localized Non-Hodgkin's Lymphoma: comparison of Chemotherapy (CHOP) to Chemotherapy plus Radiation Therapy.

Start Date 13 May 88	Est Comp Date:
Principal Investigator:	Facility:
Timothy J. O'Rourke, LTC, MC	Brooke Army Medical Center
Dept/Svc:	Associate Investigators:
Department of Medicine/Oncology	Richard O. Giudice, MAJ, MC
Key Words:	
Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0
Total Number of Subjects Enrolled to Date: 0
Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To establish the complete response rate (CR%), CR duration, survival and toxicity of chemotherapy using Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (CHOP) (eight cycles) versus CHOP (three cycles) plus radiation therapy in a cooperative group setting for patients with localized diffuse large cell lymphoma (DLC).

2) To determine if the difference in CR rates of combined treatment (less chemotherapy alone translates into longer survival with less toxicity.

3) To determine if subgroups (based on location, histology, age, stage) have significant prognostic importance with regard to CR%, time to progression, survival and toxicity.

4) To establish CR%, time to progression and survival for localized histologies other than diffuse large cell lymphoma .

Technical Approach: All patients must have biopsy proven Stage I or IE or non-bulky Stage II or IIE non-Hodgkin's lymphoma. Patients must have intermediate or high grade histology other than lymphoblastic lymphoma. No prior chemotherapy or radiation therapy is allowed. Patients with known AIDS syndrome or HIV associated complex are not eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8737 Status: Ongoing

Title: Phase III AZQ 24-Hour Infusion Versus BCNU for Adult High Grade Gliomas.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Gliomas, high-grade	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the activity of 24-hour infusion AZQ versus a BCNU control for adult, high grade, supratentorial gliomas. Primary endpoints for evaluation will be survival and time to progression. Secondary endpoints, when evaluable, will be partial and complete response rates as determined by contrast enhanced CT scan. Identification of a 50% increase in survival over control is sought.

2) To develop a data base on current surgical practices with protocol patients and to study further the prevalence and management of pulmonary toxicity from BCNU.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study has entered 18 patients at a rate of four per month for the last three months. The projected entry rate to complete the study in a timely fashion was eight per month. Toxicity to date has been primarily myelosuppression, with Grade IV toxicity seen on the fourth course of AZQ. All patients on the BCNU arm have had baseline pulmonary function tests performed at the time of entry.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8738 Status: Ongoing

Title: Treatment of Extensive Non-Small Cell Lung Cancer: Standard Dose Cisplatin Versus High-Dose Cisplatin in Hypertonic Saline Alone Versus High-Dose Cisplatin/Mitomycin-C.

Start Date 9 Sep 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Non-Small Cell, Lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 7

Total Number of Subjects Enrolled to Date: 7

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare standard dose cisplatin chemotherapy to high-dose cisplatin in hypertonic saline alone to high-dose cisplatin/mitomycin C in a randomized study, with stratification for known important prognostic factors, with regard to response rate, response duration and survival duration.

2) To compare the toxicities of these three chemotherapy regimens in patients with extensive non-small cell lung cancer.

Technical Approach: Patients with metastatic disease are eligible. this includes patients with metastases to the lung. This does not include patients whose only metastases are to the ipsilateral hilar nodes and/or mediastinal nodes, or to the supraclavicular nodes only. All patients must have pathologically demonstrated advanced non-small cell lung cancer of the following histologic types: squamous cell, adenocarcinoma or large cell carcinoma. All patients must have bidimensional (perpendicular diameters) objectively measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8741 Status: Ongoing

Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Refractory Carcinoma of the Breast.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma Breast, Refractory	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To obtain preliminary evidence of the antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with refractory carcinoma of the breast.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8742 Status: Ongoing

Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Metastatic Sarcoma.

Start Date 9 Sep 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Sarcoma, Metastatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To obtain preliminary evidence of antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with metastatic sarcomas.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Patients must have pathologically verified soft tissue sarcoma or bony sarcoma which is surgically nonresectable, metastatic to a site or sites distant from the primary lesion. All patients must have bidimensionally measurable disease.

Patients with lymphoma("reticulum sarcoma"), Kaposi's sarcoma and mesothelioma are ineligible.

Patients treated with zero or one previous chemotherapy regimen are eligible. Those who have been treated with previous biologics or immunotherapy are ineligible.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8743 Status: Ongoing

Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Metastatic Colorectal Adenocarcinoma.

Start Date 12 Aug 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Colorectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 3

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To obtain preliminary evidence of the antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with gastric adenocarcinoma.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Patients must have histologically confirmed diagnosis of colorectal adenocarcinoma. They must have metastatic or recurrent disease incurable by surgery or radiation therapy and bidimensionally measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This study is closed to new patient accrual. However it remains open for followup purposes. There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8744 Status: Ongoing

Title: A Phase II Study of Recombinant tumor Necrosis Factor (rTNF) In Patients With Refractory Multiple Myeloma.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Myeloma, multiple, refractory	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To obtain preliminary evidence of the antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with refractory and relapsing multiple myeloma.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8750 Status: Ongoing

Title: Pilot Study to Examine Cytogenetic Abnormalities in Patients with Acute Leukemia, Ancillary

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, Acute, Ancillary	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To develop the capability for group-wide cytogenetic studies in leukemia within the Southwest Oncology Group with performance of studies at an institutional level followed by a central review of the data.

2) To organize a panel of expert cytogenetics within the Southwest Oncology Group that will form the core of the central cytogenetic review process.

3) To estimate the percentage of cases that are properly prepared and for which the central review confirms the local analysis.

4) To compare the cytogenetic abnormalities present in individual patients with acute leukemia registered on companion therapeutic protocols over this one year pilot period.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8752 Status: Ongoing

Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients With Endometrial Cancer.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, endometrial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To obtain preliminary evidence of the antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with endometrial cancer.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8754 Status: Ongoing

Title: Evaluation of Didemnin B in Disseminated Malignant Melanoma, Phase II.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Melanoma, Phase II Disseminated, Malignant	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To evaluate the response rate of disseminated malignant melanoma treated with didemnin B.

2) To assess the qualitative and quantitative toxicities of didemnin B administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8755 Status: Completed
Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Pancreatic Adenocarcinoma.

Start Date 12 Aug 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Pancreatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1
Total Number of Subjects Enrolled to Date: 1
Date of Periodic Review 16 Oct 89 Results Completed

Objective(s): 1) To obtain preliminary evidence of the antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with pancreatic adenocarcinoma.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Patients must have histologically confirmed diagnosis of pancreatic adenocarcinoma. Patients must have bidimensionally measurable disease. Prior surgery and/or radiation therapy is acceptable. Patients must no have had prior chemotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time, this study is still undergoing evaluation.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8760 Status: Ongoing

Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Gastric Adenocarcinoma.

Start Date 12 Aug 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Gastric	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To obtain preliminary evidence of the antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with gastric adenocarcinoma.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Patients must have histologically confirmed diagnosis of gastric adenocarcinoma. Patients must have bidimensionally measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8788 Status: Ongoing

Title: Phase III Evaluation of "High Dose" versus "Standard Dose" Cisplatin Combined with Bleomycin and VP-16 for Advanced Metastatic Testicular Cancer.

Start Date 11 Mar 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Testicular	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To examine the value of "high dose" cisplatin (CDDP) versus "standard dose" CDDP in the regimen CDDP plus VP-16 plus bleomycin in advanced metastatic testicular cancer.

Technical Approach: all patients must have a histologic diagnosis of either advanced stage disseminated germ cell tumor, advanced extra gonadal germ cell tumor, or advanced metastatic testicular cancer.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Dctail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8789 Status: Ongoing

Title: A Randomized Study of Etoposide + Cisplatin and Etoposide + Carboplatin (CBDCA) in the Management of Good Risk Patients With Advanced Germ Cell Tumors.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Tumor, advanced germ cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): To determine in a randomized trial the differences in response, toxicity, time to relapse and survival between two active chemotherapy regimens, etoposide + cisplatin and etoposide + carboplatin, for good risk patients with germ cell tumors.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Of the 115 patients registered to date, 20 are from Southwest Oncology Group participants. The toxicity between the two arms has been similar. All seminoma patients are eligible. The study remains open.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8788 Status: Ongoing

Title: Phase III Evaluation of "High Dose" versus "Standard Dose" Cisplatin Combined with Bleomycin and VP-16 for Advanced Metastatic Testicular Cancer.

Start Date 11 Mar 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Cancer, Testicular	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To examine the value of "high dose" cisplatin (CDDP) versus "standard dose" CDDP in the regimen CDDP plus VP-16 plus bleomycin in advanced metastatic testicular cancer.

Technical Approach: all patients must have a histologic diagnosis of either advanced stage disseminated germ cell tumor, advanced extra gonadal germ cell tumor, or advanced metastatic testicular cancer.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Dctail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8789 Status: Ongoing

Title: A Randomized Study of Etoposide + Cisplatin and Etoposide + Carboplatin (CBDCA) in the Management of Good Risk Patients With Advanced Germ Cell Tumors.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Tumor, advanced germ cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): To determine in a randomized trial the differences in response, toxicity, time to relapse and survival between two active chemotherapy regimens, etoposide + cisplatin and etoposide + carboplatin, for good risk patients with germ cell tumors.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Of the 115 patients registered to date, 20 are from Southwest Oncology Group participants. The toxicity between the two arms has been similar. All seminoma patients are eligible. The study remains open.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8790 Status: Ongoing

Title: A Randomized Trial of Adjuvant Intraperitoneal Recombinant Interferon Alpha-2 in Stage III Ovarian Carcinoma in Patients who have no Evidence of Disease after Surgery and Chemotherapy.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Carcinoma, Ovary	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To assess the efficacy of alpha-2 interferon as an adjuvant to surgery and chemotherapy upon overall disease-free survival as well as number of relapses and site of relapse in patients with no evidence of disease but at substantial risk for subsequent recurrence.

Technical Approach: Patients must have a histologically confirmed diagnosis of Stage III ovarian carcinoma and must be found to be disease-free at second look surgery after treatment on SWOG 8412 or SWOG 8501; or after treatment on any other regimen that contains at least six courses of cisplatin or carboplatin.

Therapy will follow the schema outlined in the study protocol.

Progress: Only 10 patients have been registered to this study. If the accrual does not improve consideration will be given to closing this trial.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8791 Status: Ongoing

Title: (INT-0087) "Adjuvant Trial of Soft Tissue Sarcomas, Phase III."

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Sarcomas, Phase III Soft Tissue	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To assess whether adjunctive chemotherapy with adriamycin, DTIC, and ifosfamide/mesna can improve the survival and disease-free survival of selected patients with soft tissue sarcomas.

2) To establish a repository of frozen sarcoma tissue to be used for ancillary genetic and flow cytometric analysis of these tumors.

Specific goals of genetic analysis are to determine the alterations and expression of proto-oncogenes, kinases, growth factors, and growth factor receptors in Grade III adult sarcomas, to correlate these findings with various clinical parameters, and to determine if they provide independent prognostic information above that provided by stage and histologic type.

The goals of flow cytometric analysis are to determine the various patterns of ploidy and the proliferative activity of Grade III adult sarcomas and to correlate these findings with various clinical parameters. It is anticipated that with sufficient data, a model predicting survival may be derived from a combination of DNA ploidy patterns, size and location both for patients receiving and not receiving chemotherapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8792 Status: Ongoing

Title: Phase III Study of Alfa-n1 (Wellferon^{tm}) as Adjuvant Treatment for Resectable Renal Cell Carcinoma

Start Date FY 1987	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, renal cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): To assess in a controlled fashion the effectiveness of interferon alfa-n1 (Wellferon^{tm}) as a surgical adjuvant in patients with renal cell carcinoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Forty-five patients have been registered by the Southwest Oncology Group as of April 1989.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8793 Status: Ongoing

Title: Randomized Phase III Evaluation of Hormonal Therapy versus Observation in Patients with Stage D1 Adenocarcinoma of the Prostate Following Pelvic Lymphadenectomy and Radical Prostatectomy.

Start Date 13 May 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Adenocarcinoma, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To determine the time to progression and survival, in patients with histologically confirmed Stage D1 prostate cancer following prostatectomy and pelvic lymphadenectomy treated immediately with hormonal therapy.

2) Determine whether the effects of early hormone therapy on local control of D1 prostate cancer.

Technical Approach: Patients must have histologically confirmed diagnosis of adenocarcinoma of the prostate (not including "endometroid" carcinoma). Patients must have pathologic D1 disease. Histological confirmation of pelvic node involvement is required fro a patient to be considered to have Stage D1 disease. Confirmation must be obtained by formal pelvic node dissection.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8794 Status: Ongoing

Title: Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy.

Start Date 16 Oct 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian Thompson, MAJ, MC
Key Words: Carcinoma, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare in a randomized study, the disease-free survival rates in completely resected patients with pathologic stage C (T3NOMO) carcinoma of the prostate assigned to be treated with adjuvant external beam radiotherapy to that in patients assigned to receive no adjuvant therapy.

2) To assess the qualitative and quantitative toxicities of patients with pathologic stage C (T3NOMO) carcinoma of the prostate when treated with external beam radiotherapy.

Technical Approach: Patients must have undergone radical prostatectomy and pelvic lymphadenectomy with a histologically proved diagnosis of pathologic stage C (T3NOMO) carcinoma of the prostate. Patients must be able to begin treatment within 14 weeks after radical prostatectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8795 Status: Ongoing

Title: Randomized Prospective Comparison of Bacillus Calmette-Guerin and Mitomycin-C Therapy and Prophylaxis in Superficial Transitional Cell Carcinoma of the Bladder, with DNA Flow Cytometric Analysis, Phase III.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Bladder Superficial, Transitional Cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): The overall objective of this protocol is to compare the efficacy and toxicity of two commonly used intravesical treatments for recurrent transitional cell carcinoma. The treatments to be evaluated are Mitomycin-C (MMC), and Tice substrain of Bacillus Calmette-Guerin (BCG).

1) The primary objective of this study is to compare the efficacy of MMC in preventing recurrence of superficial stage Ta and T1 transitional cell carcinoma of the bladder with that of BCG.

2) To compare the survival and cause-specific survival of patients randomized to each treatment arm.

3) To compare the toxicity of each treatment with respect to local effects of cystitis, bladder contraction, and hematuria as well as systemic effects including hypersensitivity, infection, bone marrow suppression, and others.

4) To compare treatments with respect to the pathologic grade and stage of recurring tumors.

5) To compare treatments with respect to differences in flow cytometry histogram findings of tumors before treatment and at the time of recurrence.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8796 Status: Ongoing

Title: Combination Chemotherapy for Advanced Hodgkin's Disease, Phase III Intergroup.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Hodgkin's Disease, Advanced	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the effectiveness of the MOPP/ABV Hybrid with sequential MOPP -> ABVD in patients with advanced or recurrent Hodgkin's disease and to determine which regimen is superior with respect to the following parameters: A) complete response rate; B) duration of complete response; C) freedom from progression; D) survival.

2) To prospectively correlate doses of chemotherapy administered with clinical outcome.

3) To analyze and compare the toxicity and patient tolerance on each of the above two treatment programs.

Technical Approach: Patients must have histologic confirmation of Hodgkin's disease (Ann Arbor classification). All patients entered must have the tissue from which the diagnosis of Hodgkin's disease was made sent to the SWOG Pathology Office for review and classification immediately following registration.

Therapy will follow the schema outlined in the study protocol.

Progress: No major problems have been reported in the intergroup study. Accrual goals should be met during this year.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8804 Status: Ongoing

Title: Evaluation of Cis-Platinum and DTIC in Inoperable Stage III and Stage IV Melanoma, Phase II.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Melanoma, Inoperable	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): To evaluate the response rate and efficacy of DTIC and cisplatin in combination for patients with inoperable Stage III or Stage IV melanoma.

Technical Approach: Patients must have measurable, histologically confirmed metastatic melanoma with disseminated (Stage IV) or inoperable regional (Stage III) disease. Patients must have adequate renal, hepatic, and hematologic function, and a performance status of 0-2.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has now accrued 51 patients, not all of whom are evaluable. To date, there have been six partial responders out of approximately 28 evaluable patients.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8805 Status: Ongoing

Title: Neoadjuvant Cisplatin and VP-16 plus Concurrent Chest and Optional Brain Irradiation for Patients with Stage III Non-small Cell Lung Carcinoma, A Phase II Pilot.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Lung Stage III, Non-Small Cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To assess the feasibility and toxicity of treating patients with Stage III non-small cell lung cancer with cisplatin and VP-16 for two cycles, concurrent with a program of continuous, fractionated chest and optional whole brain irradiation, followed by surgical resection.

2) To assess the objective response rate, resectability rate, and proportion of patients free of microscopic residual disease after such an approach.

3) To assess whether immunocytochemical analysis and/or DNA analysis (ploidy, proliferative fraction) define subset(s) of patients who benefit from this combined modality approach, and to potentially assess the impact of chemoradiotherapy on the ploidy of the tumor.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8806 Status: Ongoing

Title: A Phase II Study of Recombinant Tumor Necrosis Factor (rTNF) in Patients with Advanced Bladder Cancer.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Bladder, Advanced	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To obtain preliminary evidence of the antitumor effects of recombinant tumor necrosis factor (rTNF) administered to patients with advanced bladder cancer.

2) To assess the tolerance and toxicity of rTNF.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8809 Status: Ongoing

Title: A Phase III Study of Alpha Interferon Consolidation Following Intensive Chemotherapy With ProMACE-MOPP (Day 1-8) in Patients With Low Grade Malignant Lymphomas.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphomas, malignant, low grade	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the disease-free survival of patients with low grade malignant lymphoma who receive alpha interferon consolidation therapy after intensive induction with chemotherapy ± radiation therapy, to those who receive induction therapy alone.

2) To determine the complete response rate, response duration and survival of low grade lymphoma patients treated with ProMACE-MOPP (Day 1-8).

3) To compare the toxicities of induction and induction plus consolidation therapy in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study has accrued 23 patients. Since the first patient was actually entered after January 1, 1989, accrual data are very preliminary. Several comments have been received regarding the difficulty in obtaining lymphangiograms and whether they truly impact on treatment decisions. The lymphangiogram requirement will, therefore, be removed. In addition, multiple tests to be performed during the interferon maintenance phase appear excessive and will be reduced.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8810 Status: Ongoing

Title: Six courses of 5-Fluorouracil and Cis-platinum with Correlation of Clinical Cellular DNA Parameters in Patients with Advanced, Untreated and Unresectable Squamous Cell Carcinoma of the Head and Neck Phase III.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Richard O. Giudice, MAJ, MC
Key Words: Carcinoma, Head and Neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) Evaluate, following three and six courses of treatment the likelihood of increased numbers of patients achieving complete response rates when given three additional courses of the same regimen.

2) Evaluate the qualitative and quantitative toxicities of 5-fluorouracil and cisplatin following three and six courses of treatment.

3) Evaluate by serial biopsy and flow cytometry the correlation of the cellular DNA parameters of degree of aneuploidy (DNA index) and proliferative activity (SPF) with patient clinical characteristics, tumor morphology, cytotoxic response, disease free interval and survival.

Technical Approach: Patients must have a histologically confirmed diagnosis of advanced unresectable squamous cell carcinoma of the head and neck Stages T4, N0-3, M0 or T2-3, N2-3, M0. Each patient will be examined by a multi-modality team prior to entry on study. Patients must be staged as having measurable disease within one week prior to entry on study.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8812 Status: Ongoing

Title: "Treatment of Limited Small Cell Lung Cancer with Concurrent Chemotherapy, Radiotherapy, with or without GM-CSF and Subsequent Randomization to Maintenance Interferon or No Maintenance."

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Limited Small Cell, Lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) Patients with limited stage small cell lung cancer (SCLC) will receive induction chemotherapy (cisplatin + VP-16 ± GM-CSF) and concurrent chest radiotherapy. This study is designed to answer two questions:

Induction/Consolidation.

- To compare the days of neutropenia (absolute granulocyte counts <500/ ul), the days of leukopenia (leukocyte counts <1,000/ ul), the incidence and severity of infections, the incidence and duration of fever, the days on antibiotics, and the days of hospitalization between patients receiving GM-CSF and those not receiving GM-CSF.
- To evaluate the toxicities of GM-CSF in patients randomized to receive it.

2) Maintenance.

- To evaluate the ability of rHuIFN Alpha-2a to prolong remission duration and survival.
- To evaluate the toxicities of rHuIFN Alpha-2a.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8814 Status: Ongoing

Title: Phase III Comparison of Adjuvant Chemoendocrine Therapy with CAF and Concurrent or Delayed Tamoxifen to Tamoxifen Alone in Postmenopausal Patients with Involved Axillary Lymph Nodes and Positive Receptors.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast, Receptor Positive	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare disease-free survival and overall survival of postmenopausal primary breast cancer patients with involved axillary nodes and positive estrogen and/or progesterone receptors treated with standard adjuvant therapy with long-term tamoxifen, or with chemoendocrine therapy with CAF, followed by long-term tamoxifen, or with concurrent chemoendocrine therapy with tamoxifen and CAF.

2) To compare the relative toxicity of the three therapies.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8816 Status: Ongoing

Title: Study of 13-cis Retinoic Acid (Accutane) Plus rIFN-alpha A (Roferon-A) in Mycosis Fungoides, Phase II.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Fungoides, Mycosis, Phase II	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To evaluate the response rate of mycosis fungoides (cutaneous T-cell lymphoma) treated with the drug combination of 13-cis Retinoic Acid (Accutane) plus rIFN-alpha A (Roferon-A).

2) To assess the qualitative and quantitative toxicities of the regimen in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8819 Status: Ongoing

Title: Central Lymphoma Repository Tissue Procurement Protocol

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma, central Tissue, repository	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Ongoing

Objective(s): 1) To acquire fresh snap-frozen lymphoma tissue to establish a central lymphoma tissue repository.

2) To establish a standard set of procedures for routine acquisition, banking, and study of lymphoma tissues within the cooperative group.

3) To use repository tissue to establish clinical correlations via presently activated phenotyping studies and future projected molecular studies assessing specimen DNA and RNA status.

4) To determine if pretreatment phenotype or genotype predict patient outcome with respect to complete response rate, time to progression, and survival using prospective trial designs.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8829 Status: Ongoing

Title: Evaluation of Amonafide in the Treatment of CNS Tumors Phase II.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Tumors, CNS	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) The objectives of this phase II study of amonafide in patients with cancer in the central nervous system are to:

- evaluate the response rate and duration of response in order to assess whether amonafide should be advanced to further studies and

2) Evaluate the qualitative and quantitative toxicities of amonafide.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8833 Status: Ongoing

Title: Phase II Investigation of Chlorambucil and Fludarabine Monophosphate in Relapsed or Refractory Chronic Lymphocytic Leukemia.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, Chronic Lymphocytic,	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To estimate the maximum tolerated dose (MTD) of Fludarabine monophosphate (FAMP) when given in combination with chlorambucil for patients with relapsed or refractory chronic lymphocytic leukemia (CLL).

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8835 Status: Ongoing

Title: Intraperitoneal Mitoxantrone vs. Intraperitoneal FUdR in Ovarian Cancer Patients with Minimal Residual Disease After Second-Look Surgery. A Randomized Phase II Pilot.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Ovarian	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Ongoing

Objective(s): 1) To establish toxicity parameters for treatment regimens given intraperitoneally.

2) To evaluate the time to disease progression, sites of disease progression, and relapse rate of ovarian cancer patients with minimal residual disease after second-look surgery in the setting of a randomized phase II trial.

3) To evaluate the survival durations of patients on the two study arms.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8851 Status: Ongoing

Title: Phase III Comparison of Combination Chemotherapy (CAF) and Chemonormonal Therapy (CAF + Zoladex or CAF + Zoladex + Tamoxifen) in Premenopausal Women with Axillary Node-Positive, Receptor-Positive Breast Cancer --Intergroup.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast, Receptor-Positive	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the recurrence rates, disease-free intervals (DFI), and hormone-receptor-positive survival for premenopausal women with axillary lymph node-positive breast cancer given adjuvant therapy with chemotherapy (CAF) alone or chemotherapy (CAF) followed by Zoladex (Z) or chemotherapy (CAF) followed by Zoladex plus Tamoxifen (Z + T). We will compare CAF with CAF + Z and CAF + Z with CAF + Z + T.

2) To compare the relative toxicities of these 3 regimens.

3) To assess the effect of CAF, CAF + Z, and CAF + Z + T on hormone levels (LH, FSH, and estradiol) in premenopausal women treated with these adjuvant therapies.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8854 Status: Ongoing

Title: Prognostic Value of Cytometry Measurements of Breast Cancer DNA from Postmenopausal Patients with Involved Nodes and Receptor Positive Tumors: A Companion Protocol to SWOG 8814.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Ongoing

Objective(s): 1) To determine if ploidy analysis of breast cancer by routine clinical flow cytometry (FCM) technique can predict response to therapy and survival of patients registered to SWOG-8814.

2) To determine if ploidy analysis by image processing technique more accurately predicts patient response to therapy and survival than ploidy analysis by FCM.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: .. s is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8891 Status: Ongoing

Title: Low-Grade Glioma Phase III: Surgery and Immediate Radiotherapy vs Surgery and Delayed Radiotherapy.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Glioma, Low-Grade, Phase III	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) In adult patients with low-grade supratemporial glioma, to compare the effect on survival of radiation therapy (RT) administered immediately after pathological diagnosis with RT administered on progression as measured by clinical and/or radiographic (CT scan) and/or MRI.

2) To compare quality of survival in patients receiving immediate RT with that in patients receiving delayed RT.

3) In a cohort of adult patients with low-grade glioma whose disabling neurologic signs and symptoms require that they be treated with RT immediately, to evaluate biological and clinical variables which might predict prognosis.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8892 Status: Ongoing

Title: A Study of Radiotherapy With or Without Concurrent Cisplatin in Patients with Nasopharyngeal Cancer, Phase III

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Nasopharyngeal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the complete response rate, time to treatment failure, overall survival and pattern of recurrence.

2) To assess the qualitative and quantitative toxicities

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8896 Status: Ongoing

Title: Phase III Protocol for Surgical Adjuvant therapy of Rectal Carcinoma: A Controlled Evaluation of A: Protracted Infusion 5-Fluorouracil as a Radiation Enhancer and B: 5-FU Plus Methyl-CCNU Chemotherapy.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, rectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare the local recurrence rates, rates of distant metastasis, disease-free survival, and overall survival in patients having potentially curative resections of modified Astler Coller B_{2-3} and C_{1-3} rectal carcinoma treated with sequential chemotherapy and radiotherapy using 5-FU as a radiation enhancer given either by simple IV bolus administration or by Protracted Venous Infusion (PVI) concomitant with radiation therapy.

2) To compare the same study endpoints for the same group of patients who either receive Methyl-CCNU as a component of the systemic therapy regimen or do not receive Methyl-CCNU as a component of the systemic chemotherapy regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8897 Status: Ongoing

Title: Phase III Comparison of Adjuvant Chemotherapy with or without Endocrine Therapy in High-Risk, Node Negative Breast Cancer Patients, and a Natural History Follow-up Study in Low-Risk, Node Negative Patients (Intergroup).

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast, Node Negative	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To compare disease-free survival (DFS) and overall survival(s) of high risk primary breast cancer patients with negative axillary lymph nodes treated with standard adjuvant chemotherapy with CMF for six cycles or with chemotherapy using CAF for six cycles.

2) To assess the value of the addition of tamoxifen for five years compared to no tamoxifen in these patients.

3) To compare the relative toxicity of the therapies.

4) To assess the prognostic significance of DNA flow cytometry in patients with small, occult invasive breast cancer treated by local therapy only.

5) To evaluate the disease free survival and survival of low risk invasive breast cancer determined by receptor status, tumor size and % of S phase treated by local therapy only.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8899 Status: Ongoing

Title: A Prospectively Randomized Trial of Low-Dose Leucovorin Plus 5-FU, High-Dose Leucovorin Plus 5-FU, or Observation Following Curative Resection in Selected Patients with Duke's B or C Colon Cancer.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Colon, Duke's B/C	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To assess the effectiveness of 5-FU + low-dose Leucovorin, and 5-FU + high dose Leucovorin as surgical adjuvant therapy for resectable colon cancer, when compared to surgery alone.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8900 Status: Ongoing
Title: A Phase II Pilot of VAD and VAD/Verapamil for Refractory Myeloma.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Myeloma, Refractory	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0
Total Number of Subjects Enrolled to Date: 0
Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To estimate the response rate and response duration with chemotherapy alone (VAD) and chemotherapy plus the chemo-modifier, verapamil (VAD/V), in patients who have failed previous combination chemotherapy.

2) To investigate the toxicities of these two treatments.

3) To evaluate the presence and prognostic significance of Ki-67 and P-glycoprotein in multiple myeloma.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8905 Status: Ongoing

Title: Phase II/III Study of Fluorouracil (5FU) and its Modulation in Advanced Colorectal Cancer.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Colorectal, Advanced	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To determine and compare response rates and toxicities of 5-fluorouracil given by different schedules and/or with biochemical modulators to patients with advanced colorectal cancer.

2) To compare patient survival on the different 5-FU regimens.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8912 Status: Ongoing

Title: Evaluation of Fazarabine in Patients with Recurrent Squamous Cell Carcinoma of the Head and Neck.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Head/Neck, Squamous Cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) Evaluate the response rate of recurrent squamous cell carcinoma of the head and neck when treated with fazarabine.

2) Assess the qualitative and quantitative toxicities of bolus fazarabine administered on a daily x 5 schedule.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: SWOG 8925 Status: Ongoing

Title: Evaluations of Cisplatin + VP-16 Followed by Mitotane at Progression if No Prior Mitotane or Cisplatin + BP-16 Only if Prior Treatment with Mitotane in Advanced and Metastatic Adrenal Cortical Carcinoma.

Start Date FY 1989	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Metastatic Adrenal Cortical	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 89 Results Continue

Objective(s): 1) To evaluate the response and response duration of patients with:

- adrenocortical carcinoma treated with combination chemotherapy consisting of cisplatin and etoposide, and
- of those who receive mitotane after progression on the above chemotherapy (if no prior treatment with mitotane).

2) To evaluate the qualitative and quantitative toxicities of these therapies.

3) To evaluate and compare tumor morphology of patients with this rare tumor.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, no reportable data available.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 7799 Status: Ongoing

Title: Rare Tumor Registry for Childhood Solid Tumor Malignancies.

Start Date 25 Sep 81	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Solid tumor malignancies	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 13 Feb 89 Results Continue

Objective(s): 1) To collect natural history data on malignancies which occur so rarely that large series of patients cannot be accumulated any single institution.

2) To evaluate therapies in those groups of rare tumors in which fair numbers of cases can be accrued.

Technical Approach: Any child under the age of 18 years at diagnosis with a rare solid tumor is eligible for the study.

Progress: One patient remains on this study. No reportable data are available.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8104 Status: Ongoing

Title: Comprehensive Care of the Child with Neuroblastoma: A Stage and Age Oriented Study, Phase III.

Start Date 27 Jan 83	Est Comp Date:
Principal Investigator Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Neuroblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 8

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To treat the tumor according to age and stage at which the tumor was diagnosed.

2) To reduce later complications by separating by age and stage those patients that require surgery only; surgery and chemotherapy; surgery, chemotherapy, and radiation therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Two patients remain on the study. Three have been transferred to other areas. One patient transferred here on this study relapsed.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8304 Status: Ongoing	
Title: SIMAL #4. Combination Chemotherapy for Remission Induction and Maintenance for: 1) Recurrent Childhood Lymphocytic Leukemia After Elective Cessation of Therapy; 2) Children with Occult Testicular Leukemia After 3 Years of Continuous Complete Remission.	
Start Date 27 Jan 84	Est Comp Date:
Principal Investigator Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Leukemia, lymphocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 13 February 1989 Results Continue	

Objective(s): 1) To compare the effectiveness of two regimens of cyclic maintenance chemotherapy in children with ALL, who relapse 6 months or greater, after elective cessation of chemotherapy.

2) To evaluate the effectiveness of prophylactic intrathecal chemotherapy, during the second remission.

3) To compare the effectiveness of two regimens of cyclic maintenance chemotherapy in patients with testicular leukemia.

4) To determine the effectiveness of two regimens of cyclic maintenance chemotherapy in children with isolated CNS relapse.

Technical Approach: Patients less than 21 years of age with pathologic verification of leukemic relapse at any site more than six months after elective cessation of initial therapy are eligible. Children with their first CNS relapse are also eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 8 Nov 89 Proj No: POG 8315 Status: Ongoing

Title: Laboratory Study and Subclassification of Non-Hodgkin's Lymphoma.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To provide a mechanism for the group wide study of biologic characteristics of lymphoma cells, by acquisition and coordination of data from reference laboratories.

2) To seek correlates of biologic charcteristics, with histopathology, clinical presentation, and end results of protocol therapies.

3) To attempt the development of a comprehensive classification of childhood NHL which is both clinically and biologically relevant.

Technical Approach: Patients less than 21 years of age with tumor tissue or cells available for study who are simultaneously being entered on open, front-end POG treatment protocols for NHL are eligible for this study.

Progress: Two patients have been entered on study with satisfactory samples for classification.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8340 Status: Ongoing

Title: Allogeneic or Autologous Bone Marrow Transplantation (BMT) for Stage D Neuroblastoma: A POG Pilot Study

Start Date 12 Aug 85	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC,	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics/Medicine	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC John J. Posch, Jr. Barbara Reeb
Key Words: Transplantation, bone marrow, autologous	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 3

Total Number of Subjects Enrolled to Date: 18

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To determine the response rate and duration of patients aged > 1 year with metastatic (Stage D) neuroblastoma to intensive chemotherpay and fractionated total body irraadiation followed by allogeneic or autologous bone marrow transplantation (BMT) performed in first clinical remission.

2) To determine the response rate and duration using the same regimen in patients with Stage D neuroblastoma who fail to respond to, or recur after, conventional chemotherapy.

3) To determine the toxicity of the above regimen.

Technical Approach: This pilot study tests the efficacy and toxicity of high dose melphalan and fractionated total body irradiation supported by allogeneic or autologous BMT for neuroblastoma in first clinical remission or following relapse.

Bone marrow aspiration and therapy will follow the schema outlined in the study protocol.

Progress: Eighteen patients have been transplanted. There have been 4 early deaths, 13 successful engraftments, and 1 partial engraftment. Overall disease free survival is 6/18 (33%). Overall survival is 7/18 (39%). Disease free survival for patients transplanted when in complete response 3/7 (43%) and 3/11 (27%) for patients transplanted not in complete response.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8398 Status: Ongoing

Title: Up-front Alternating Chemotherapy for Acute Lymphocytic Leukemia in Childhood

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): To determine the toxicity and complications, short and long term, of alternating intensive chemotherapy pairs in children with acute lymphocytic leukemia of poor prognosis. The intensive chemotherapy pairs are: 6-MP/MTX; VM-26/Ara-C; and Daunomycin/Ara-C.

Technical Approach: To be eligible for this study, patients must be registered on POG 8600. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on the study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8451 Status: Ongoing

Title: Intergroup Rhabdomyosarcoma Study III

Start Date 1 Feb 85	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): To compare various forms of therapy of rhabdomyosarcoma based on favorable and non-favorable histology.

Technical Approach: Patients under 21 years of age with the diagnosis of rhabdomyosarcoma or undifferentiated sarcoma, type indeterminate, or extraosseous Ewing's sarcoma, are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient died after multiple relapses of the tumor. One patient continues to to do well.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8493 Status: Ongoing
Title: Infant Leukemia Protocol

Start Date 26 Mar 85	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0
Total Number of Subjects Enrolled to Date: 0
Date of Periodic Review 12 February 1988 Results Continue

Objective(s): 1) To establish the qualitative and quantiative toxicity of this regimen in infants and to determine criteria for dose modificaiton in infants.

2) To obtain an estimate of survival and disease-free survival in infants $\leq$12 months of age treated with intensive chemotherapeutic regimen.

Technical Approach: Patients with ALL (or undifferentiated leukemia) $\leq$12 months of age at diagnosis are eligible. All patients must comply with immunologic and cytogenetic criteria for diagnosis according to POG front line ALinC classification studies and must be registered on that study as well as this protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8495 Status: Ongoing

Title: A Phase I Study of Hyperfractionation in Brain Stem Gliomas in Children

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Brain stem gliomas	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): 1) To test the feasibility of treating children with brain stem gliomas with hyperfractionated (twice daily) radiotherapy.

2) To study the immediate and late side effects of such treatment.

3) To test the feasibility of escalation of the dose of radiotherapy in this situation.

4) To monitor the response of the patients in terms of tumor regression, disease free interval, and length of survival.

Technical Approach: Patients >3 and <21 years of age with a previously untreated tumor arising in the mesencephalon, pons, including the cerebellar peducles and floor of the IVth ventrical, and medulla oblongata and with a life expectancy of greater than 6 weeks, shall be eligivel for inclusion in this study. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on the study.

Detail Summary Sheet

Date: 28 Nov 88 Proj No: POG 8532 Status: Ongoing

Title: Treatment of Intracranial Ependymomas

Start Date 31 May 85	Est Comp Date:
Principal Investigator (vice Pick) Paul J. Thomas, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words: Ependymoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 12 February 1988 Results Continue

Objective(s): To estimate the occurrence of subarachnoid seeding in children with well differentiated, IVth ventricular epndymoma following resection and posterior foss irradiation.

Technical Approach: Patients $\geq$24 months and $\leq$21 years with histologically confirmed primary intracranial ependymomas or ependymoblastoma are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8552 Status: Ongoing

Title: A Case-Control Study of Childhood Rhabdomyosarcoma

Start Date 31 May 85	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To evaluate the relationships between environmental exposures and childhood rhabdomyosarcoma (RMS).

2) To evaluate associations between gestational factors and childhood RMS.

3) To evaluate the role of genetic factors in the etiology of childhood RMS.

4) To develop new methods for using subjects from collaborative cancer clinical trials for etiologic research.

Technical Approach: This is a case-control study of childhood RMS which will identify its cases from a large national collaborative clinical trial. The study will reexamine several promising hypotheses suggested by the preliminary study of RMS.

Progress: No reportable data are available.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8561 Status: Ongoing

Title: Phase II Study of 6-Mercaptopurine Administered as an Intravenous Infusion for Malignant Solid Tumors and Acute Leukemia

Start Date 2 Aug 85	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Solid Tumors Acute leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To determine response rate of children with advanced malignatn disease for whom no effective anti-cancer therapy is known to treatment with 6-mercaptopurine (6-MP) administered as a 48 hour IV infusion.

2) To further assess the toxicity in a larger group of children.

Technical Approach: Patients must be $\leq$ 21 years of age with a measurable solid tumor or acute leukemia with either an M3 marrow or extra medullary disease. The diagnosis must be confirmed by appropriate histologic examination.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8600/01/02 Status: Ongoing

Title: Evaluation of Treatment Regimens in Acute Lymphoid Leukemia in Childhood (AlinC #14) - A Pediatric Oncology Group Phase III Study

Start Date 28 Mar 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, lymphoid	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 6

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To test the concept that intensive asparaginase (ASP) therapy, designed to maintain low asparagine levels for the first six months of maintenance will improve the outcome of patients with standard risk acute lymphocytic leukemia (ALL) when added to pulses of intermediate dose methotrexate (MTX), as compared to intensification with IDM alone.

2) To study the effectiveness in standard risk patients of intensification with a potentially synergistic or additive drug pair, i.e., IDM plus AraC, as compared to that of intensification with IDM pulses alone.

3) To determine if administering a pulse of IDM + AraC at 3 week intervals during the first 4 months of complete remission in children with ALL is superior to administering the same number of IDM + AraC pulse at 23-week intervals during the first 2 years of complete remission in children with ALL with either "lower" or "higher" risk of relapse.

4) To obtain further information on the immediate and delayed toxicity of the continuation of chemotherapy program that incorporates these combinations of MTX and AraC or MTX and ASP in moderately high doses.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: All patients entered remain in remission.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8615 Status: Ongoing

Title: A Phase III Study of Large Cell Lymphomas in Children and Adolescents: A Comparison of Two Treatment Regimens - ACOP+ vs AOP

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To determine the influence of alkylating agent (cyclophosphamide) therapy in advanced-stage large cell lymphomas in children and adolescents, by comparing in a randomized prospective study the efficacy and toxicity of a modified ACOP+ versus a modified APO regimen.

2) To reduce the adverse effects of treatments by elimination of involved field and cranial radiation in the treatment of large cell lymphomas.

3) To evaluate the adequacy of one year of total therapy for advanced large cell Non-Hodgkin's lymphoma (NHL).

4) To study clinical pathologic patterns and biologic characteristics of large cell lymphomas in children and adolescents.

Technical Approach: Previously untreated patients under 21-years of age, available for periodic follow-up are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8616 Status: Ongoing

Title: Intensive Chemotherapies for Stage III Diffuse Undifferentiated Lymphoma (DU NHL Burkitt and Non-Burkitt)

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To achieve chemotherapeutic cure (two-year disease-free survival) in a majority of patients with Stage III DU NHL.

2) To determine if a new regimen, Total Therapy B, is superior to high-dose Cytoxan, high-dose methotrexate for patients with Stage III DU NHL.

3) To study potential interaction between treatment and LDH.

Technical Approach: Previously untreated patients under 21 years of age with a diagnosis of diffuse, undifferentiated non-Hodgkin's lymphoma, small non-cleaved cell (Burkitt or non-Burkitt), Stage III by Murphy's system will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8617 Status: Ongoing

Title: Therapy for B-Cell Acute Lymphoblastic Leukemia and Advanced Diffuse Undifferentiated Lymphomas

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, acute lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To estimate the complete remission (CR) rate in patients with Stage IV diffuse undifferentiated non-Hodgkin's Lymphoma (DU NHL) and B-Cell acute lymphocytic leukemia (B-ALL) with a new schedule of administration of 3 active agents: "split-dose" cycolophosphamide (cyclo) - Adriamycin (Adria) + vincristine (VCR).

2) To estimate the chemotherapeutic cure rate in Stage IV DU NHL and B-ALL with a brief (6 month) intensive rotational chemotherapy program designed to confer greater protection against central nervous system (CNS) disease and marrow relapse.

3) To estimate the reinduction rate and disease-free survival rate for patients in relapse with non-lymphoblastic lymphoma.

Technical Approach: Patients must be under 21 years of age at time of initial diagnosis in order to be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered on study had an initially good response but relapsed after about six months and died.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8622 Status: Ongoing

Title: Evaluation of Retinoic Acid in Pediatric Patients with Non-lymphocytic Leukemia

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, non-lymphocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To determine the effectiveness and further assess the toxicity of 13-cis retinoic acid (RA) in the treatment of children with acute non-lymphocytic leukemia (ANLL).

2) To explore the association of RA-induced differentiation in vitro with the response to RA in vivo if there is evidence of response in patients with ANLL.

Technical Approach: Patients under 21 years of age at time of diagnosis who have ANLL in bone marrow relapse who have been resistant to other forms of therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8625/26 Status: Ongoing

Title: Combined Therapy and Restaging in the Treatment of Stages I, IIA, and $IIIA_1$ Hodgkin's Disease in Pediatric Patients

Start Date 30 Jul 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Hodgkin's disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To compare the effectiveness of 3 cycles of MOPP/ABVD vs 2 cycles of MOPP/ABVD plus low dose radiation therapy in terms of duration or remission and eventual survival (with one cycle = 1 course MOPP and 1 course of ABVD) in children with early stage Hodgkin's disease.

2) To compare the incidence and severity of acute/long-term toxicity of MOPP/ABVD vs MOPP/ABVD plus involved field, low dose radiation therapy.

3) To evalute the incidence of CR after 2 cycles of MOPP/ABVD.

4) To search for prognostic factors that may correlate with duration of survival.

5) To determine the salvage rate of patients who fail to respond to 2 cycles of MOPP/ABVD or who fail to achieve a CR after completion of prescribed therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: One patient has completed treatment and continues to do well.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8631 Status: Ongoing

Title: Medulloblastoma Favorable Prognosis: Randomized Study of Reduced Dose Irradiation to Brain and Spinal Contents vs Standard Dose Irradiation - A Phase III Study.

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Medulloblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To determine patterns of recurrence, disease free survival, and survival in patients with favorable prognosis medulloblastoma who receive a neuraxis dose of 2340 rad compared to those who recieve 3600 rad.

2) To study the quality of survival obtained by decreasing the dose of radiotherapy to cerebrum and spinal cord.

3) To evaluate prospectively the central nervous system (CNS) functions of these children with IQ tests, CT scans, neurological examinations, psychometric testing and neuroendocrine tests.

Technical Approach: Patients $\geq$36 months and $\leq$21 years of age at diagnosis are eligible. Patients must have no evidence of dissemination beyond the posterior fossa confirmed by myelogram, chest x-ray, bone scan, bone marrow and CSF exam, i.e. M_0.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8633/34 Status: Ongoing

Title: Treatment of Children 3 years of Age with Malignant Brain Tumors Using Postoperative Chemotherapy and Delayed Irradiation.

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To determine if the use of postoperative chemotherapy in children less than 36 months of age with malignant brain tumors will allow for the delay of cranial irradiation for 12 months in children 2-3 years at diagnosis and 24 months for those <2 years old.

2) To estimate the response (CR or PR) to two cycles of cyclophosphamide and vincristine in children with measurable tumor at the initiation of chemotherapy.

3) To estimate the objective response rate (CR, PR, SD) and disease control interval with this multi-agent chemotherapy regimen.

8634 - To estimate the response rate, disease control interval, recurrence-free survival and survival of those children who, after having progression of disease on chemotherapy (#8633), are subsequently treated with surgery and radiation therapy or radiation therapy alone.

Technical Approach: Inclusion-exclusion criteria and therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8638 Status: Ongoing

Title: Randomized Phase II Study of Carboplatin (CBCDA) vs CHIP in the Treatment of Children with Progressive or Recurrent Brain Tumors

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Brain tumor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To determine the effectiveness of Carboplatin (CBCDA) and CHIP in the treatment of children with progressive or recurrent brain tumors.

2) To compare the toxicities associated with the use of each agent.

Technical Approach: To be eligible for this study, the patient must be $\leq$21 years of age at initial diagnosis, with a recurrent or progressive brain tumor, and who has not been entered on more than one phase II new agent study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 7 Nov 89	Proj No: POG 8650	Status: Ongoing

Title: National Wilms' Tumor Study - 4: Stage I/Favorable or Anaplastic Histology

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Wilms' tumor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): To gain a better understanding of the Wilms' tumor by gathering detailed information regarding gross and histologic morphology and to correlate this information with treatment and clinical outcome.

Technical Approach: Patients will be randomized according to stage and histology.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered as a "followed" patient because the primary was non-resectable. Two additional patients were transferred here as "followed" patients. Two patients have relapsed while on therapy.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8651 Status: Ongoing

Title: Osteosarcoma #2: A Randomized Trial of Pre-Surgical Chemotherapy vs Immediate Surgery and Adjuvant Chemotherapy in the Treatment of Non-Metastatic Osteosarcoma.

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Osteosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): To determine whether chemotherapy administered prior to and after the definitive surgery of the primary tumor can improve the disease-free and/or overall survival of patients with non-metastatic osteosarcoma of the extremity or resectable bone when compared to the traditional approach of surgical treatment of the primary tumor followed by adjuvant chemotherapy.

Technical Approach: To be eligible for this study, the patient must be under 30 years of age, have no prior history of cancer and no prior therapy other than biopsy.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8653/54 Status: Ongoing

Title: A Study of Soft Tissue Sarcomas Other than Rhabdomyosarcoma and Its Variants

Start Date 30 Jul 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To determine whether adjuvant chemotherapy with vincristine, Adriamycin, cyclophosphamide, and actinomycin D (VACA) increases the relapse-free survival (RFS) of patients with localized soft tissue sarcoma (STS) who are in complete response (CR) status after surgery with or without postoperative radiation.

2) To compare VACA with VACA plus DTIC (VACAD) therapy in regard to CR and RFS rates in patients with: (a) metastatic STS at diagnosis or (b) previously "untreated" recurrent STS (patients on the no chemotherapy control arm of "adjuvant" study 8653) or (c) localized persistent gross residual sTS after surgery and radiation therapy.

Technical Approch: Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 7 Nov 88 Proj No: POG 8661 Status: Ongoing

Title: Evaluationof CHIP in Malignant Solid Tumors, A Phase II Study

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1988 Results Continue

Objective(s): 1) To evaluate the response rate to CHIP in patients with recurrent malignant tumors resistant to conventional therapy.

2) To evaluate the toxicity of CHIP in these patients.

Technical Approach: To be eligible for this study, the patient must be $\leq$21 years of age, have a life expectancy of $\geq$4 weeks and absence of significant uncontrolled infection.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 7 Nov 88 Proj No: POG 8691 Status: Ongoing

Title: T-Cell #3 Pilot Study

Start Date 30 Jul 86	Est Comp Date:
Principal Investigator Paul J. Thomas, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Allen R. Potter, LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To determine the toxicity and complications associated with the administration of this intensive chemotherapy regimen to children with T-ell leukemia and advanced stage T-cell lymphoma.

2) To determine the feasibility of using this chemotherapy regimen as the backbone of a randomized groupwide T-cell study evaluating intensive L-asparaginase therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been entered. On patient achieved remission but relapsed after about one year. The other patient remains on therapy with good response.

This study has been closed to new entries; however, it remains open for follow-up and continued therapy of the one patient who has responded.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8693 Status: Completed

Title: VP-16, AMSA + 5-Azacytidine in Refractory ANLL

Start Date 27 Mar 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Closed

Objective(s): 1) To determine the toxicity of VP-16, AMSA combination on patients with refractory ANLL.

2) To determine the toxicity of the three drug combination - VP-16, AMSA and 5-Azacytidine.

Technical Approach: Patients with ANLL $\leq$ 21 years of age at the time of initial diagnosis who have either failed to respond to induction therapy or who have relapsed will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered on this study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8695 Status: Ongoing

Title: A POG Pilot Study of Front Loading Chemotherapy in Children with Increased Risk Medulloblastoma

Start Date 19 Dec 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Medulloblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To evaluate the feasibility and acute toxicity of chemotherapy prior to radiation therapy in the treatment of newly diagnosed children with medulloblastoma who are at increased risk for recurrence.

2) To measure tumor response to the entire chemotherapy regimen of cis-platinum, vincristine, and high-dose cyclophosphamide prior to irradiation.

3) To evaluate the feasibility of a centralized rapid neuroradiology review of pre-study CT scans and myelograms in determining patient eligibility.

Technical Approach: To be eligible for this study, patients must be >3 years and <21 years of age and must have presence of advanced medulloblastoma.

Therapy will follow the schema outlined in the study protocol.

Progress: No patient have been entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8696/97 Status: Ongoing

Title: Treatment of Hepatoblastoma (HB) with Surgery and Chemotherapy and Radiation Therapy

Start Date 30 Jul 86	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Hepatoblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To obtain preliminary data on the natural disease course of patients with carefully staged, completely resected, "favorable histology" hepatoblastoma, given no further therapy after surgery.

2) To obtain preliminary data on the toxicity of a combination of cis-platin, vincristine and 5-fluorouracil (DDP/VCR/5-FU) in the treatment of patients with hepatoblastoma.

3) To assess tumor response to DDP/VCR/5-FU in those patients with Stage III and IV hepatoblastoma.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 7 Nov 89	Proj No: POG 8704	Status: Ongoing

Title: T-Cell #3 Protocol - A POG Phase III Study

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To estimate the disease-free survival of a multiagent chemotherapy regimen designed to be particularly effective for patients with T-cell derived lymphoid malignancies in children with advanced stage lymphoblastic lymphoma and T-cell acute lymphoblastic leukemia.

2) To determine the efficacy of adding intensive high-dose L-asparaginase to the backbone chemotherapy regimen in an attempt to improve disease-free survival.

Technical Approach: Patients <21 years and >12 months with a diagnosis of ALL or patients age <21 years with a diagnosis of lymphoblastic lymphoma will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient with lymphoblastic lymphoma was entered, has achieved a satisfactory remission, and remains on treatment.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8710 Status: Ongoing

Title: Protocol for Second Induction and Maintenance in Childhood Acute Lymphoblastic Leukemia (SIMAL #5)

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): 1) To compare disease-free survival of a regimen including MTX/VM-26 with a control regimen.

2) To compare disease-free survival of a regimen including IFN with a control regimen.

Technical Approach: Therapy will follow the schema outlined in the study protocol

Progress: No patients enrolled to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8719 Status: Ongoing

Title: Trial of Shortened Therapy without Maintenance for the Treatment of Localized Non-Hodgkin's Lymphoma

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator (vice Potter) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To determine if 24 weeks of maintenance chemotherapy with daily oral 6-MP and weekly methotrexate contributes to relapse-free survival and survival for patients with localized non-Hodgkin's lymphoma when aadded to a 9 week induction and consolidation regimen as administered in 8314.

2) To maintain a high cure rate with minimum toxicity for children with localized non-Hodgkin's lymphoma in favorable sites.

Technical Approach: Patients <21 years of age at time of diagnosis will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8725 Status: Ongoing

Title: Randomized Study of Intensive Chemotherapy (MOPP/ABVD) +/- Low Dose Total Nodal Radiation Therapy in the Treatment of Stages IIB, $IIIA_2$, IIIB, and IV Hodgkin's Disease in Pediatric Patients.

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): To determine, in a randomized study, whether the addition of low dose total nodal radiation therapy (TNRT) in pediatric patients with Hodgkin's disease who have achieved a complete remission after receiving 4 courses of MOPP alternating with 4 courses of ABVD will improve the duration of complete remission and survival when compared to patients who have received chemotherapy alone.

To determine whether TNRT will significantly increase either acute toxicity or long-term morbidity when compared to MOPP/ABVD alone.

To determine the effect of chemotherapy as compared to chemotherapy plus TNRT on splenic function as determined by the pitted erythrocyte count using Nomarski optics.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8726 Status: Ongoing

Title: Alpha-Interferon in Histiocytosis X and Other Non-Malignant Histiocytic Disease, Phase II

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Histiocytosis X	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To evaluate the response rate of patients with histiocytosis X and related diseases to treatment with alpha interferon (α-IFN).

2. To determine the toxicities of α-IFN in children with histiocytosis X and related diseases.

Technical Approach: Eligible patients must have biopsy-proven diagnosis of reac tive histiocytosis and must be <21 years of age at time of protocol entry.

Therapy will follow the schema outlined in the study protocol.

Progress. No patients entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8731 Status: Ongoing

Title: Phase II Study of Low-dose "Continuous" Oral Methotrexate in the Treatment of Children with Progressive or Recurrent Brain Tumors.

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): To determine the effectiveness of low-dose "continuous" oral methotrexate in the treatment of children with progressive or recurrent brain tumors and to evaluate the toxicity associate with the use of this agent given in this manner.

Technical Approach: Therapy will follow the schema outlined in the study protocol

Progress: No patients have been entered to date

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8739 Status: Ongoing

Title: Evaluation of Alpha Interferon in the Treatment of Recurrent Brain Tumors in Children, Phase II

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Brain tumor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To determine the efficacy of alpha$_2$-interferon (-IFN) in children with recurrent brain tumors resistant to standard therapy in regard to response rate of different histologic subtypes to -IFN.

2) To further assess the toxicity of -IFN in children.

Technical Approach: To be eligible for this study, patient must be <21 years of age with a biopsy-proven diagnosis of astrocytoma, malignant glioma, brainstem glioma, medulloblastoma or ependymoma with clear evidence of progression or recurrence.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8741/42 Status: Ongoing

Title: Stage D NBL #3: Treatment of Stage D Neuroblastoma in Children >365 Days at Diagnosis

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Neuroblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): To evaluate response rates and toxicity of four sequentially administered Phase II chemotherapy agents when given prior to conventional therapy in patients >365 days of age with Stage D (metastatic) neuroblastoma. The specific agents to be studied are: ifosfamide, carboplatin (CBDCA), cis-dichloro-transdihydroxy-bis-platinum (CHIP), and epirubicin.

Technical Approach: Any patient with newly diagnosed metastatic (Stage D) neuroblastoma who is >365 days and <21 years of age, who has receive no previous chemotherapy or irradiation therapy, and who has measurable disease will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC entered to date. One patient transferred here on study remains on study and has had a complete response.

Detail Summary Sheet

Date: 7 Nov 89	Proj No: POG 8743	Status: Ongoing

Title: Treatment in 'Better Risk' Neuroblastoma: POG Stge B (All Ages) and POG Stage C, D, and DS (VS) <365 Days

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Neuroblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To prospectively identify patients <365 days of age at diagnosis who will fail to achieve CR with cycophosphamide (CYC) and Adriamycin (ADR) and delayed surgery; then to alter therapy in these patients and evaluate the CR and survival rates with alternate therapy, using cis-platinum (CDDP) and VM-26.

2) To evaluate the disease-free survival (DFS) and survival in a larger group of patients currently considered to be "better risk" patients with neuroblastoma.

Technical Approach: Patient eligibility and therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8751 Status: Ongoing

Title: Low-Dose Methotrexate in the Treatment of Rhabdomyosarcoma, Phase II

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To determine the response rate of children with rhabdomyosarcoma treated with low-dose methotrexate (LDMTX) given every 6 hours for 8 doses, followed by leucovorin rescue.

2) To determine the type and duration of toxicity of low-dose sustained oral methotrexate.

Technical Approach: To be eligible for entry into this study, patient must be <21 years of age and have biopsy-proven rhabdomyosarcoma unresponsive to standard therapy for which there is no known potentially curative therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8759 Status: Ongoing

Title: The Effectiveness of Phase II Agents in Untreated Metastatic Osteosarcoma (MOS) or Unresectable Primary Osteosarcoma vs Previously Treated Recurrent Osteosarcoma

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Osteosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To estimate the response rate to Ifosfamide in patients presenting with metastatic osteosarcoma or unresectable primary osteosarcoma prior to treatment of those patients with other chemotherapeutic reagents.

2) To estimate the response rate to Ifosfamide in previously treated patients with osteosarcoma.

3) To explore the feasibility and toxicity of the addition of Ifosfamide to a multi-agent combination chemotherapy regimen which includes drugs known to be active in the treatment of osteosarcoma.

4) To study the DNA content of primary and metastatic tumors.

Technical Approach: In order to be eligible for this study, patient must be <30 years of age with no prior history of cancer for Stratum 1 or no prior history of cancer other than osteosarcoma for Stratum 2.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8760 Status: Ongoing

Title: Trimetrexate in the Treatment of Childhood Acute Leukemia, Phase II.

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): To determine the remission rate obtained with the administration of trimetrexate to children with acute lymphoblastic or acute myelogenous leukemia which is retractory to standard therapy and to further evaluate the toxicity of trimetrexate in children.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8761 Status: Ongoing

Title: A Phase II Study of Homoharringtonine for the Treatment of Children with Refractory Non-Lymphoblastic Leukemia

Start Date 25 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, non-lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): 1) To evaluate the efficacy of Homoharringtonine for the therapy of refractory acute nonlymphoblastic leukemia (ANLL) in children.

2) To assess the toxicity of Homoharringtonine in chidren.

Technical Approach: In order to be eligible for this study patients must be <21 years of age with a diagnosis of ANLL. They must have a life expectancy of >4 weeks and evidence of recovery from toxicity of prior therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8763 Status: Ongoing

Title: Evaluation of Response and Toxicity of Ifosfamide and VP-16-213 in Children with Resistant Malignant Tumors

Start Date 3 Sep 87	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 3

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): To determine the antitumor activity and toxicity of ifosfamide (IFX) plus Etoposide (VP-16) against malignant solid tumors resistant to conventional chemotherapy.

Technical Approach: Eligible patients must be <21 years of age and have documented measurable disease, confirmed with appropriate histologic examination. Patients must have progressive or recurrent disease that is resistant to conventional therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Three patients have been entered on study. One patient with recurrent Ewing's sarcoma had no response. One patient with recurrent Wilms' tumor had an initial partial response then recurred. One patient with recurrent Wilms' tumor is too early to evaluate for response.

Detail Summary Sheet

Date: 7 Nov 89	Proj No: POG 8764	Status: Ongoing

Title: Chemotherapy Regimen for Early and Initial Induction Failures in Childhood Acute Lymphoblastic Leukemia: Phase II Study

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): To estimate the complete remission rate for early and initial induction failures in childhood ALL based on an induction regiment of VM-26 and continuous infusion cytosine arabinoside (ara-C).

To estimate the one-year disease-free survival for early and initial induction failures in childhood ALL, based on a new regimen.

To try and better characterize this unique subpopulation of patients with primary drug resistnace using cDNA probes fot the multidrug-resistant phenotype and obtain an oncogene profile.

Technical Approach: Patient eligibility and therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 7 Nov 89	Proj No: POG 8788 Status: Ongoing
Title: Intergroup Rhabdomyosarcoma Study IV Pilot Study for Clinical Group III Disease	
Start Date: 13 May 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To determine the feasibility of, and toxicity associated with using vincristine-actinomycin D-ifosfamide (VAI) or vincristine-ifosfamie-etoposide (VIE) as induction and continuation chemotherapies.

2) To determine a dose of cyclophosphamide to be used in VAC therapy which will result in myelosuppression comparable to that experienced with the VAI regimen.

3) To determine the feasibility of/and toxicity associated with using a hyperfractionated radiotherapy program following induction chemotherapy in children above and below age 6.

Technical Approach: Patients <21 years of age at diagnosis with Clinical Group III pathologically-proven rhabdomyosarcoma or undifferentiated sarcoma, or extraosseous Ewing's sarcoma are eligible for this study. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8820 Status: Ongoing

Title: VP-16, AMSA+/1 5-Azacytidine in Refractory ANLL, Phase II/III

Start Date: 13 Mar 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Refractory ANLL	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): 1) To compare, in a randomized study, the remission rate of VP-16/AMSA versus VP-16/AMSA/5-AZA in children with recurrent or refractory acute non-lymphocytic leukemia (ANLL).

2) To determine the duration of remission, using pulses of the induction regimen as continuation therapy.

3) To study the relative toxicites of these two therapies.

Technical Approach: Patients $\leq$ 21 years of age at the time initial diagnosis who have either failed to respond to induction therapy or who are in first relapsed are eligible for this study. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8821 Status: Ongoing

Title: AML#3 Intensive Multiagent Therapy vs. Autologous Bone Marrow Transplant Early in 1st CR for Children with Acute Myelocytic Leukemia.

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): To determine the disease-free survival (DFS) and event-free survival (EFS) in childhood acute myelocytic leukemia (AML) offered by intensive chemotherapy with alternating non-cross resistant drug combinations for nine courses.

To determine if short (three course) intensive chemotherapy (identical to the first three courses of the above regimen) followed by autologous bone marrow transplant (BMT) using the Busulfan/Cytoxan preparative regimen and 4-Hydroxycyclophosphamide (4-HC) purged marrow is effective therapy.

To compare, in a randomized study, the results of the above 2 regimens and to correlate the treatment outcome with clinical and laboratory features.

Technical Approach: Patient eligibility and therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been sent here for autologous bone marrow transplant and will return to their parent institution when received.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8823 Status: Ongoing

Title: Recombinant Alpha-Interferon in Childhood Chronic Myelogenous Leukemia, Phase II

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, myelogenous	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): To determine toxicity, response rate and duration of response to therapy with recombinant alpha interferon for newly diagnosed "adult" chronic myelogenous leukemia (ACML) in chronic phase, and for "juvenile" chronic myelogenous leukemia (JCML) occurring within the first two decades.

Technical Approach: Eligible patinets must have been $\leq$ 21 years of age at the time of initial diagnosis and must not have received prior anti-neoplastic therapy. Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8827 Status: Ongoing

Title: Treatment of Children with Hodgkin's Disease in Relapse, Phase II

Start Date: 17 Oct 88	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Hodgkin's disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): To estimate the response rate of a new combination chemotherapy regimen consisting of cytosine arabinoside, cisplatin, and VP-16 in children who have relapsed Hodgkin's disease and to determine the toxicity associated with this regimen.

Technical Approach: Patients with relapsed Hodkin's disease who were $\leq$21 years of age at time of inidial dianosis are eligible. Patients must not have responded or have relapsed after two or more courses of MOPP and two courses of ABVD, either given together or sequentially. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8828 Status: Ongoing

Title: Late Effects of Treatment of Hodgkin's Disease, Non-therapeutic Study

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Hodgkin's disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review _____ Results _____

Objective(s): To estimate the incidence of various late effects seen in patients with Hodgkin's disease treated by the regimens of POG 8625 and POG 8725. In particular, to focus on known sequelae of Hodgkin's disease and its treatment.

Technical Approach: All patients registered on front-lin phase III POG Hodgkin's disease therapeutic studies POG 8625 and POG 8725 after the opening of this study will be eligible and must be registered on this study unless the patient or parent/guardian refuses.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8829 Status: Ongoing

Title: A Case-Control Study of Hodgkin's Disease in Childhood - A Non-therapeutic Study

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Hodgkin's disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): To conduct the first interview case-control study of childhood Hodgkin's disease to learn more about the epidemiology of the disease in children.

Technial Approach: All pediatric oncology patients, less than 15 years of age, with a newly confirmed diagnosis of Hodgkin's disease are eligible. Telephone interview and adminstration of questionnaire will be conducted.

Progress: This is a new study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8832 Status: Ongoing

Title: Pre-Irradiation Combination Chemotherapy with Cisplatin and ARA-C for Children with Incompletely Resected Supratentorial Malignant Tumors, Phase II

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Tumors, CNS	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): 1) To determine acute, subacute, and combined-treatment toxicities of chemotherapy with cisplatin and Ara-C followed by cranial irradiation in children.

2) To estimate the efficacy of a 15-week period of chemotherapy with cisplatin and Ara-C in children with malignant supratentorial (CNS) tumors.

3) To estimate the feasibility and completeness of second surgical resection in children with incompletely-resected malignant supratentorial tumors after treatment with initial chemotherapy.

Technical Approach: Patients $\geq$ 3 years and $\leq$ 21 years at diagnosis are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8833 Status: Ongoing

Title: Pre-radiation Chemotherapy in the Treatment of Children with Brain Stem Tumors - A Phase II Study

Start Date 29 Jul 88	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 13 February 1989 Results Continue

Objective(s): To evaluate the response of children with brain stem gliomas to four courses of combination high-dose cyclophosphamide and cis-platinum prior to radiation therapy. Response will be measured by CT and/or MRI scan and neurological exam.

To monitor possible acute and chronic toxicities of the chemotherapy, including neurological and audiological toxicity. To assess unusual irradiation-related toxicity post-chemotherapy.

To Estimate the disease control interval for the population under study following chemotherapy and radiation therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered to date.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8844 Status: Ongoing

Title: Stage D Neuroblastoma #4: Bone Marrow Transplant in the Treatment of Children > 365 Days at Diagnosis with Stage D Neuroblastoma

Start Date: 12 Dec 88	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Neuroblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): 1) To determine whether the outcome of children > 365 days with Stage D neuroblastoma who are treated at institutions offering an autologous bone marrow transplant (ABMT) option to conventional therapy and who have good initial response to conventional therapy, is better than the outcome of similar children who are treated at institutions which do not offer the transplant option.

2) To evaluate the toxicities associated with this protocol.

Technical Approach: Patients >365 days and <21 years at diagnosis previously registered on POG 8741/42 who have completed post-induction evaluation and post-induction surgery are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 7 Nov 89	Proj No: POG 8850	Status: Ongoing

Title: Evaluation of Vincristine, Adriamycin, Cyclophosphamide, and Dactinomycin with or without the Addition of Ifosfamide and Etoposide in the Treatment of Patients with Newly-diagnosed Ewing's Sarcoma or Primitive Neuroectodermal Tumor of Bone, Phase III

Start Date: 13 Mar 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Ewing's sarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): To determine the event-free survival and survival of patients with Ewing's sarcoma and PNET of the bone who are treated with etoposide and ifosfamide in combination with standard therapy, and to compare their EFS and survival rates with those of patients treated with standard therapy alone.

Technical Approach: Patients <30 years of age with newly diagnosed Ewing's sarcoma, PNET of bone, or a diagnosis compatible with primitive sarcoma of bone are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8861 Status: Ongoing

Title: The Efficacy of MESNA in Preventing a Recurrence of Cyclophosphamide-induced Hemorrhagic Cystitis

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Cystitis, hemorrhagic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): To determine whether mesna can prevent the recurrence of acute, cyclophosphamide-induced hemorrhagic cystitis in patients in whom continued therapy with cyclophosphamide is medically indicated.

Technical Approach: Patients who develop hematuria during, or within a 24 hour period immediately following, the administration of cyclophosphamide being administered for a disease in which cyclophosphamide is generally accepted as appropriate therapy are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8862 Status: Ongoing

Title: Treatment of First Marrow Relapse and/or Extramedullary Relapse of Childhood Acute T-Lymphoblastic Leukemia and T-Non-Hodgkin's Lymphoma with Combination Chemotherapy including 2'-Deoxycoformycin, Phase II

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: T-lymphoblastic leukemia T-Non-Hodgkin's lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): 1) To assess the toxicity and efficacy of low dose deoxycoformycin (DCF) given as IV bolus injection in prolonging the duration of remission for patients with T-ALL/T-NHL in second remission.

2) To determine the correlation of clinical responses and toxicities with plasma levels of adenosin deaminase (ADA), adenosin (ado) and Deoxyadenosine (dado), dATP/ATP ratios in RBCs, and in vitro sensitivity of leukemia cells to DCF plus dado.

3) To determine the efficacy of IV methotrexate and Iv 6-mercaptopurine in patients with T-ALL and T-NHL.

Tehcnical Approach: Patients < 21 years of age at time of diagnosis in first relapsed documented by aspirate or biopsy are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8863 Status: Ongoing

Title: High Dose Cytosine Arabinoside in the Treatment of Advanced Childhood Tumors Resistant to Conventional Therapy, Phase II

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): To determine whether high dose cytosine arabinoside is effective in the treatment of advanced childhood tumors resistant to conventional therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8865 Status: Ongoing

Title: Recombinant Alpha-Interferon in Relapsed T-Cell Disease, Phase II

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: T-cell ALL/Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): 1) To determine the response rate to α-IFN in children with T-cell ALL/Lymphoma who have failed standard therapy.

2) To correlate the response rate to the presence of interferon receptors, oncogene expression, modulation of oncogene expression by interferon, DNA content, and antiproliferative effect of IFN in vitro on T-cell lymphoblasts.

Technical Approach: Patients <21 years of age at initial diagnosis and in relapse with T-ALL or T-NHL are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8866 Status: Ongoing

Title: Polyethylene Glycol-Conjugated L-Asparaginase in Combination with Standard Agents as Second-Line Induction Therapy for Children with Acute Lymphoblastic Leukemia in Bone Marrow Relapse, Phase II

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review_____ Results_____

Objective(s): To compare, in a randomized trial, the efficacy, toxicity and feasibility of administrtion of PEG-L-asparaginase versus native L-asparaginase as part of a standard combination chemotherapy re-induction regimen for children with ALL in second relapse.

Technical Approach: Eligible patients must have been <21 years of age at initial diagnosis and must have ALL in second marrow relapse. Therapy will follow the schema outlined in the study protocol.

Progres: This is a new study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8889 Status: Ongoing

Title: Intergroup Rhabdomyosarcoma Study-IV Pilot Study for Clinical Group IV Disease

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To determine the feasibility of, and toxicity associated with, using ifosfamide-doxorubicin (ID) as induction chemotherapy and subsequently, as part of maintenance chemotherapy with vincristine-actinomycin D - cyclophosphamide (VAC) for rhabdomyosarcoma and similar sarcomas and to determine the feasibility of/and toxicity associated with hyperfractionated radiotherapy program following induction chemotherapy.

Technical Approach:Patients <21 years of age at diagnosis with pathologically-proven rhabdomyosarcoma or undifferentiated sarcoma, or extraosseous Ewing's sarcoma are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8930 Status: Ongoing

Title: A Comprehensive Genetic Analysis of Brain Tumors

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Brain tumor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To determine prospectively the clinical significance of abnormalities of cellular DNA content, as measured by flow cytometry and to determine the clinical implications of cytogenetic abnormalities in pediatric brain tumors.

Technical Approach: Any patient with a brain tumor who has had tumor tissue submitted for study and who is subsequently registered on a POG frontline therapeutic protocol is eligible for this study.

Progress: This is a new study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8935 Status: Ongoing

Title: A Sxudy of the Biological Behavior of Optic Pathway Tumors, Phase II

Start Date: 10 Jul 89	Est Comp Date:
Principa Investigator Allan R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Optic pathway tumors	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): 1) To assess time to progression of optic pathway tumors (OPTs).

2) To estimate the response rate of radiation therapy in children with OPTs, when measured at 2 years post-irradiation.

Technical Approach: Patients <21 years of age at the time of diagnosis with imaging evidence of intraorbital or chiasmatic mass with or without visual loss are eligible. Within two weeks following surgery, slides will be submitted to pathology for review.

Progress: This is a new study.

Detail Summary Sheet

Date: 7 Nov 89 Proj No: POG 8936 Status: Ongoing

Title: Phase II Study of Carboplatin (CBDCA) in the Treatment of Children with Progressive Optic Pathway Tumors

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Optic pathway tumors	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): To assess the response rate to CBDCA in children <5 years of age with optic pathway tumors and to assess the efficacy of CBDCA in delaying progression of disease.

Technical Approach: Patients will be eligible for treatment on this study if they meet the eligibility criteria for POG 8935, if they are <5 years of age and if there is evidence of progressive disease. Therapy will follow the schema youtlined in the study protocol.

Progress: This is a new study.